



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014601 SF4001

Finger clip Sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014602 SF4002

Finger clip Sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014603 SF4006

Finger clip Sensor HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014604 SF4007

Finger clip Sensor HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014605 SF4011

Finger clip Sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014606 SF4012

Finger clip Sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014607 SF4016

Finger clip Sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014608 SF4017

Finger clip Sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014609 SF4021

Finger clip Sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Date:** ...14/July/2009

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014610 SF4026

Finger clip Sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014611 SF4036

Finger clip Sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014612 SF4037

Finger clip Sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014613 SF4041

Finger clip Sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014614 SF4046

Finger clip Sensor Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014615 SF4047

Finger clip Sensor Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014617 SF4061

Finger clip Sensor Datascope compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014618 SF4062

Finger clip Sensor Datascope compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Date:** ...14/July/2009

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014619 SF4066

Finger clip Sensor Spacelabs compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014620 SF4071

Finger clip Sensor Sensormedics compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014621 SF4076

Finger clip Sensor Palco compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014650 SF6500 VM

Finger clip Sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014701 SC4001

Soft Sensor - Adult Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014702 SC4002

Soft Sensor - Adult Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014703 SC4006

Soft Sensor - Adult HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

24

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014704 SC4007

Soft Sensor - Adult HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014705 SC4011

Soft Sensor - Adult Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014706 SC4012

Soft Sensor - Adult Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014707 SC4016

Soft Sensor - Adult Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014708 SC4017

Soft Sensor - Adult Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014709 SC4021

Soft Sensor - Adult BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014710 SC4026

Soft Sensor - Adult Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014711 SC4036

Soft Sensor - Adult CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014712 SC4037

Soft Sensor - Adult CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014713 SC4041

Soft Sensor - Adult Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014714 SC4046

Soft Sensor - Adult Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014715 SC4047

Soft Sensor - Adult Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014717 SC4061

Soft Sensor - Adult Datascope compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014718 SC4062

Soft Sensor - Adult Datascope compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014719 SC4066

Soft Sensor - Adult Spacelabs compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014720 SC4071

Soft Sensor - Adult Sensormedics compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014721 SC4076

Soft Sensor - Adult Palco compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014722 SC4031

Soft Sensor - Adult Minolta compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014750 SC6500 VM

Soft Sensor - Adult Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014755 SC6501 VM

Soft Sensor - Adult Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014761 SCP4001

Soft Sensor – Paediatric Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014762 SCP4002

Soft Sensor – Paediatric Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014763 SCP4006

Soft Sensor – Paediatric HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014764 SCP4007

Soft Sensor – Paediatric HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014765 SCP4011

Soft Sensor – Paediatric Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014766 SCP4012

Soft Sensor – Paediatric Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014767 SCP4016

Soft Sensor – Paediatric Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014768 SCP4017

Soft Sensor – Paediatric Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014769 SCP4021

Soft Sensor – Paediatric BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014770 SCP4026

Soft Sensor – Paediatric Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014771 SCP4036

Soft Sensor – Paediatric CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014772 SCP4037

Soft Sensor – Paediatric CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014773 SCP4041

Soft Sensor – Paediatric Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014774 SCP4046

Soft Sensor – Paediatric Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014775 SCP4047

Soft Sensor – Paediatric Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014777 SCP4061

Soft Sensor – Paediatric Datascope compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014778 SCP4062

Soft Sensor – Paediatric Datascope compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014779 SCP4066

Soft Sensor – Paediatric Spacelabs compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014780 SCP4071

Soft Sensor – Paediatric Sensormedics compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014781 SCP4076

Soft Sensor – Paediatric Palco compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014782 SCP4031

Soft Sensor – Paediatric Minolta compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014751 SCP6500 VM

Soft Sensor – Paediatric Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014756 SCP6501 VM

Soft Sensor – Paediatric Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014801 EP4001

Ear probe Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014802 EP4007

Ear probe HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014803 EP4011

Ear probe Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

70

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014804 EP4012

Ear probe Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014805 EP4016

Ear probe Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014806 EP4046

Ear probe Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014807 EP4047

Ear probe Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014826 W-4011

Wrap Sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014836 W-4041

Wrap Sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014840 W-4061

Wrap Sensor Datascope compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014831 W-4026

Wrap Sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014825 EP6500 VM

Ear probe Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014827 W-4012

Wrap Sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014828 W-4016

Wrap Sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014841 W-4062

Wrap Sensor Datascope compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014842 W-4066

Wrap Sensor Spacelabs compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014843 W-4071

Wrap Sensor Sensormedics compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014844 W-4076

Wrap Sensor Palco compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014832 W-4031

Wrap Sensor Minolta compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014822 W-4002

Wrap Sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014823 W-4006

Wrap Sensor HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014835 W-6500 VM

Wrap Sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014821 W-4001

Wrap Sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014837 W-4046

Wrap Sensor Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014838 W-4047

Wrap Sensor Nihon-Kohden compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014829 W-4017

Wrap Sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

93

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014830 W-4021

Wrap Sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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94

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014824 W-4007

Wrap Sensor HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014833 W-4036

Wrap Sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014834 W-4037

Wrap Sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014845 SY6500 VM

Multi-Site Y Sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014850 XT4800

Extension cable Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014851 XT4801

Extension cable Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014852 XT4810

Extension cable HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014853 XT4811

Extension cable HP/Phillips compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014854 XT4821

Extension cable Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014855 XT4826

Extension cable Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014856 XT4831

Extension cable BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014857 XT4836

Extension cable Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014859 XT4876

Extension cable GE compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014860 XT4877

Extension cable GE compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014861 XT4901

Extension cable Draeger compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014895 XT6500

Extension cable Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014896 XT6501

Extension cable Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014901 1- AF

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014902 1- PF

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014903 1- IF

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014904 1- NF

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014905 1- AT

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014906 1- PT

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

117

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014909 1- AP

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

118

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014910 1- PP

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014911 1- IP

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:  
120

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014912 1- NP

SpO2 Disposable sensor Nellcor compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

121

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014913 2- AF

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014914 2- PF

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014915 2- IF

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014916 2- NF

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014917 2- AT

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014918 2- PT

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014921 2- AP

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014922 2- PP

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014923 2- IP

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014924 2- NP

SpO2 Disposable sensor Ohmeda compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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131

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014925 3- AF

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014926 3- PF

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014927 3- IF

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014928 3- NF

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014929 3- AT

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014930 3- PT

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014933 3- AP

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014934 3- PP

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014935 3- IP

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

140

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014936 3- NP

SpO2 Disposable sensor Datex compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

141

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014937 4- AF

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

142

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014938 4- PF

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

143

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014939 4- IF

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

144

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014940 4- NF

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

145

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014941 4- AT

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

146

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014942 4- PT

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

147

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014945 4- AP

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014946 4- PP

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014947 4- IP

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014948 4- NP

SpO2 Disposable sensor CSI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014949 5- AF

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014950 5- PF

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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153

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014951 5- IF

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

154

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014952 5- NF

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

155

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014953 5- AT

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

156

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014954 5- PT

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

157

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014957 5- AP

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

158

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014958 5- PP

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

159

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014959 5- IP

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014960 5- NP

SpO2 Disposable sensor BCI compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

161

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014961 6- AF

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

162

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014962 6- PF

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

163

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014963 6- IF

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

164

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014964 6- NF

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

165

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014965 6- AT

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014966 6- PT

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

167

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014969 6- AP

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014970 6- PP

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014971 6- IP

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014972 6- NP

SpO2 Disposable sensor Novamatrix compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

171

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014973 7- AF

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014974 7- PF

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014975 7- IF

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014976 7- NF

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014977 7- AT

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014978 7- PT

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014981 7- AP

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014982 7- PP

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014983 7- IP

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014984 7- NP

SpO2 Disposable sensor Nonin compatible

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

181

- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014985 8-AF  
  
SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:  
182

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- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014986 8-PF  
  
SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014987 8-IF

SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014988 8-NF  
  
SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... *D Lamb* **Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014989 8-AT

SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

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- Technical documentation required by the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23<sup>rd</sup> August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15<sup>th</sup> June 1994, issued by the British Standards Institute (CE0086).

**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014990 8-PT  
  
SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014993 8-AP

SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014994 8-PP  
  
SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014995 8-IP

SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014996 8-NP

SpO2 Disposable sensor Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0012101 VM2101

VM2101

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.





**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0012105 VM2105 - GRY

VM2105 – Grey

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0012106 VM2105 - ORA

VM2105 – Orange

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014590 SCA6500VM

Soft Sensor (autoclavable) - Adult Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.



**Declaration of Conformity.**

**Class IIb Medical Device(s).**

**Manufacturer:** Viamed Limited.

15 Station Road,  
Cross Hills,  
Keighley,  
West Yorkshire,  
BD20 7DT.  
United Kingdom.

**Device(s):** 0014591 SCPA6500VM

Soft Sensor (autoclavable) – Paed Viamed

**Description of Device(s):** For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14<sup>th</sup> June 1993 as transposed into National Law in the countries where the product is intended to be marketed.

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**Signed:** ..... 

**Date:** ...14/July/2009

**Position:** Managing Director.