

Technical File 27 Temperature Probes

Original Manufacturer Sensatronic GmbH Alter Holzhafen 19 – 23966 Wismar Germany
Licensed Via Bluepoint Medical to Viamed Ltd.

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EC Certificate of Conformity : 2697GB410130820

Expiry Date : 07 August 2018

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Pilatuspool 2 – 20355 Hamburg – Germany
MEDCERT Identification No. 0482

EN ISO 13485:2012 + AC:2012

Certificate : 2697GB438130820

Expiry Date : 07 August 2018

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Pilatuspool 2 – 20355 Hamburg – Germany
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- Solutions adopted to fulfill the essential requirements.
- Design input specification.
- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
- Software verification and validation reports and risk assessment EN 62304.
- Evidence of usability human factors assessment.
- Details of clinical investigations.
- Medicinal substance human blood derivatives animal tissues.
- Classification rationale.

Date November 3, 2016

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Documentation controlled by the Original Equipment Manufacturer

Blueprint medical GmbH & Co. KG

An der Trave 15
23923 Selmsdorf
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Supported by

EC Certificate of Conformity: 4026GB410141105

Expiry Date : 03 November 2017

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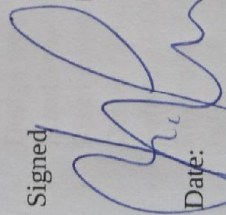
Certificate 4026GB438141105

Expiry Date: 03 November 2017

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The following documentation can be made available direct to notified bodies upon request.

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Technical File 47 Capnographs

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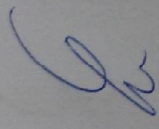
Technical File 45 Flow Sensors

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- Solutions adopted to fulfill the essential requirements.
- Design input specification.
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- Details of clinical investigations.
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Technical File 33 / 40 Finger Pulse Oximeters

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- Solutions adopted to fulfill the essential requirements,
- Design input specification.
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- Evidence of usability human factors assessment.
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- Medicinal substance human blood derivatives animal tissues.
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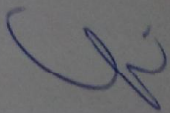
Technical File 23 Pulse Oximeters

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- Solutions adopted to fulfill the essential requirements.
- Design input specification.
- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
- Software verification and validation reports and risk assessment EN 62304.
- Evidence of usability human factors assessment.
- Details of clinical investigations.
- Medicinal substance human blood derivatives animal tissues.
- Classification rationale.

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Technical File 97 VersaStream Capnography Sampling Lines

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- Design input specification.
- Manufacturing process flow chart.
- Risk management document for the system.
- Detailed test results device verification.
- Software verification and validation reports and risk assessment EN 62304.
- Evidence of usability human factors assessment.
- Details of clinical investigations.
- Medicinal substance human blood derivatives animal tissues.
- Classification rationale.
-

Technical File 31 Pulse Oximetry Sensors - 4000 Series

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- Solutions adopted to fulfill the Essential Requirements
- Design input specification
- Manufacturing process flow chart
- Risk management document for the system
- Detailed test results Device verification
- Software verification and validation reports and risk assessment EN 62304
- Evidence of Usability Human factors assessment
- Details of Clinical investigations
- Medicinal substance human blood derivatives animal tissues
- Classification rationale

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