

DECLARATION OF CONFORMITY

Medical Device(s)

Manufacturer: **Viamed Ltd.**
15 Station Road
Cross Hills
Keighley
West Yorkshire BD20 7DT
United Kingdom

Device(s): NeoMask light occluder,

Class: I

Part number: See page 2

Description: Light occluder which is for use with phototherapy light (400 nm to 550 nm)

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/Eec (Medical Devices Directive) of the 14th June 1993 and considering the amendments by directive 2007/47/EC - as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

Certificate of Registration No. MD 78787 to ISO 13485:2003 of original registration date 27th January 2004, issued by the British Standards Institute (CE0086)

Certificate of Registration No. FS 28344 to ISO 9001:2008 of original registration date 15th June 1994, issued by the British Standards Institute (CE0086)

In accordance with 2011/65/EU RoHS Directive

In Accordance with EN ISO 10993-1:2009/AC:2010

For and on behalf of Viamed Ltd.

Signature:



Name: **Derek Lamb - Managing Director**

Date:

01 / 06 / 2017



VIAMED

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Part number: 1114015 1114016 1114017 1114020 1114021 1114022 1114025 1114026
1114027 1114030 1114031 1114032 1134015 1134016 1134017

For and on behalf of Viamed Ltd.

Signature: 

Name: **Derek Lamb - Managing Director**

Date: 01 / 06 / 2017