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## DECLARATION OF CONFORMITY Medical Device(s)

Manufacturer: Viamed Ltd.

15 Station Road Cross Hills

Keighley
West Yorkshire BD20 7DT

**United Kingdom** 

Device(s): Apgar Timer

Class:

Part number: 0310100

Description: Start Freeze Reset timer used to gauge a given time interval when scoring

newborn infants based on their vital signs and response to stimulus.

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 14<sup>th</sup> 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:

Technical documentation required by MDD (Annex VII) retained by: Viamed Ltd.

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

For and on behalf of Viamed Ltd.

Signature:

Name: Derek Lamb - Managing Director

Date: 29 / 07 / 2015