

## DECLARATION OF CONFORMITY

### Medical Device(s)

Manufacturer: **Viamed Ltd.**

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

Device(s): **V1000 Foetal Heart Simulator**

Class: **1**

Part number: **1410000**

Description: **Test equipment that allows the operation and functionality of foetal heart monitors to be assessed**

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 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: **14 / 03 / 2016**