

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 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:

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