



VIAMED

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DECLARATION OF CONFORMITY CE Class I Test Equipment

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

Device(s): V1000 Foetal Heart Simulator

Part number: 1410000

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

The Viamed V1000 Foetal Heart Simulator conforms to EN60601-1-2:1993 and the published specifications, and is designed and manufactured in accordance with Viamed's quality standards.

This declaration is supported by:

- Technical documentation retained by: Viamed Limited.
- Certificate of Registration No. MD 78787 to ISO 13485:2016 & EN ISO 13485:2016 of original registration date 27th January 2004, issued by British Standards Institute.

For and on behalf of Viamed Ltd.

Signature:

Name:

Steve Nixon - Director

Date:

6th June 2019