

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 654559
Issued To: HeraMED Ltd.
6 Meir Ariel St
POB 8576
Netanya
4250364
Israel

In respect of:

The design and manufacture of ultrasound foetal and photoplethysmographic maternal heart rate monitors.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-10-07**

Date: **2020-04-02**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 654559

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD 1302 MDS 7010	Monitoring devices for foetal and maternal heart rate	NA for class IIa device

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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6 Meir Ariel St
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Netanya
4250364
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Subcontractor:

Service(s) supplied

Crow Electronic Engineering Ltd.
HaMasger St 2
Afula
Israel

Manufacture

Obelis s.a
Bd. Général Wahis 53
1030 Brussels
Belgium

EU Representative

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Certificate History

Certificate No: **CE 654559**
 Date: **2020-04-02**
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4250364
Israel

Date	Reference Number	Action
07 October 2016	8535694	First issue.
11 July 2018	8953103	Change of address of Legal Manufacturer from HeraMED Ltd., 7 Giborei Israel, Poleg Industrial Park, Netanya, Israel to HeraMED Ltd., 6 Meir Ariel St, POB 8576, Netanya, 4059300, Israel.
15 February 2019	8674204	Traceable to NB 0086.
Current	9767446	Extension to the previous certificate scope to include maternal heart rate monitor. Zip code updated. Addition of device table. Certificate Renewal.

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