

# 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  
4059300  
Israel

In respect of:

**The design and manufacture of ultrasound foetal 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):



Albert Roossien, Regulatory Lead

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

Date: **2019-02-15**

Expiry Date: **2021-10-06**

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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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## List of Significant Subcontractors

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

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**4059300**  
**Israel**

**Subcontractor:**

**Service(s) supplied**

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Crow Electronic Engineering Ltd.  
HaMasger St 2  
Afula  
Israel

**Manufacture**

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

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 654559**  
 Date: **2019-02-15**  
 Issued To: **HeraMED Ltd.  
 6 Meir Ariel St  
 POB 8576  
 Netanya  
 4059300  
 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.
Current	8674204	Traceable to NB 0086.

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