

EC Certificate - Full Quality Assurance System

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

No. CE 682105
Issued To: **Medisafe UK Limited**
Twyford Road
Bishop's Stortford
Hertfordshire
CM23 3LJ
United Kingdom

In respect of:

Design and manufacture of ultrasonic washer/disinfector equipment for medical purposes.

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: **2018-03-27**

Date: **2019-01-03**

Expiry Date: **2023-03-26**

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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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Certificate History

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Certificate History

Date	Reference Number	Action
27 March 2018	8845792	First Issue.
Current	8846228	Traceable to NB 0086.

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