

EC Certificate - Full Quality Assurance System

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

No. CE 635727
Issued To: **Wassenburg Medical B.V.**
Edisonring 9, 6 & 8
DODEWAARD
6669 NA
Netherlands

In respect of:

Design and manufacture of washing and disinfection systems for flexible endoscopes and other re-useable thermolabile medical devices.

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **25 September 2015**

Date: **25 September 2015**

Expiry Date: **01 October 2020**

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Page 1 of 1

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 635727**
 Date: **25 September 2015**
 Issued To: **Wassenburg Medical B.V.**
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Date	Reference Number	Action
25 September 2015	8334077	First issue. Transfer from another Notified Body, upgrade to Annex II and certificate renewal

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Page 1 of 1

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