

EC Certificate - Full Quality Assurance System

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

No. CE 687158
Issued To: **Medical Enterprises Europe B.V.**
Amsterdamseweg 147A
Amstelveen
1182 GT
The Netherlands

In respect of:

Design and manufacture of microwave therapy devices and related disposable sterile sets for hyperthermia and instillation of chemotherapeutic agent.

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: **2019-05-23**

Date: **2019-05-23**

Expiry Date: **2024-05-22**

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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 687158

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD 1402 MD 1101 MDS 7010	RF device for delivery of chemotherapy under hyperthermia	Synergo® radiofrequency hyperthermia device is designed for the treatment NMIBC (non-muscle-invasive bladder cancer). The Radiofrequency-Induced Thermo-Chemotherapy Effect (RITE) on which the treatment is based, is attained through simultaneous heating of the bladder walls and intravesical instillations of a chemotherapeutic agent.
MD 1402 MD 0102	Catheter Tubing Line Set (accessory to RF device)	
Class IIa		
MD 0102	Closed Drainage Set (accessory to RF device)	N/A

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