

EC Certificate - Full Quality Assurance System

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

No. CE 544967
Issued To: **Tristel Solutions Limited**
1B Lynx Business Park
Fordham Road
Snailwell
Cambridgeshire
CB8 7NY
United Kingdom

In respect of:

The design and manufacture of impregnated disinfectant wipes and disinfectant solutions for use with invasive and non-invasive devices.
The design and manufacture of disinfection systems for use with lumened and non-lumened invasive medical devices.
Those aspects of Annex II related to securing and maintaining sterility of rinse wipes.

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: **2009-04-20**

Date: **2020-01-29**

Expiry Date: **2024-04-19**

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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 544967

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD 0108	Disinfectant wipe for Medical Devices	Impregnated wipe for disinfecting invasive and non-invasive medical devices
MD 0108	Device Disinfectant Solution for Medical Devices	Disinfectant for use on invasive and non-invasive medical devices
MD 1107	Stella disinfection system	Electronic endoscope disinfection system
Class IIa		
MD 0108	Disinfectant wipe for Medical Devices	Impregnated wipe for disinfecting non-invasive medical devices
MD 0108	Device Disinfectant Solution for Medical Devices	Disinfectant for use on non-invasive medical devices
Class Is		
MD 0108	Sterile wipe	

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