



EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 665205

Issued To: Optimum Medical Solutions Limited

Tennant Hall Blenheim Grove

Leeds LS2 9ET

United Kingdom

In respect of:

The manufacture and final inspection of sterile non-medicated lubricating jelly for invasive use.

Those aspects of Annex V concerned with securing and maintaining sterility of sterile prefilled syringes for catheter balloon inflation, sterile catheter valves, sterile ultrasound gel and sterile urinary bags.

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2017-09-15** Date: **2020-02-12** Expiry Date: **2022-09-14**

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Jany C Stade





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Supplementary Information to CE 665205

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0108	Sterile non-medicated lubricant jelly for invasive use	
Class I sterile		3 COMMENT 250
MD 0108	Sterile ultrasound gel	# 7
MD 0102	Sterile prefilled syringe for catheter balloon inflation	
MD 0102	Sterile urinary bag	
MD 0102	Sterile catheter valve	-

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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.