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 pre-filled 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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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		
MD 0108	Sterile ultrasound gel	---
MD 0102	Sterile prefilled syringe for catheter balloon inflation	---
MD 0102	Sterile urinary bag	---
MD 0102	Sterile catheter valve	---

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