

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.**

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: **2019-05-10**Expiry Date: **2022-09-14**

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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.