By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 757549 R000

Manufacturer: Optimum Medical Solutions Limited

Address:
Tennant Hall
Blenheim Grove
Leeds
LS2 9ET
United Kingdom

Single Registration Number: GB-MF-000005194

EU Authorised Representative: MT Promedt Consulting GmbH

Address:
Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graer

First Issue Date: **2022-09-19**

Current Issue Date: **2022-10-04**

Starting Validity Date: **2022-10-04**

Expiry Date: **2027-09-18**

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Device Schedule: Class III and Class IIb devices

Device(s)	Risk Classification
Medical lubricant for invasive use	For the smooth insertion of medical devices, and examinations, reducing the risk of trauma during procedures

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile Ultrasound gel	Class Is
Prefilled Sterile Water Syringes	Class Is
Sterile Urine Leg Bag	Class Is
Sterile 2l Drainage Urine Bag	Class Is
Sterile Catheter Valve	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-09-19	3515302	Issued.
Current	3774162	Supplemented – Addition of device group Medical lubricant for invasive use

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