EU Quality Management System Certificate

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

MDR 734734 R000

Manufacturer: Medical Components, Inc.

Signature Not Verified
Dokument podpisany przez Justyna Rozwadowska
Data: 2023.09.25 08:36:08 CEST

Address:
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

Single Registration Number: US-MF-000008230

EU Authorised Representative: MPS Medical Product Service GmbH

Address:
Borngasse 20
35619 Braunfels
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):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-11-08**

Current Issue Date: **2022-12-19**

Starting Validity Date: **2022-12-19**

Expiry Date: **2027-11-07**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Hemo-Flow, Jet Flow, Nipro Flow Long-Term Hemodialysis Catheter Sets	See MDR 759413
Titan HD Long-Term Hemodialysis Catheter Sets	See MDR 759420
Split Cath III Long-Term Hemodialysis Catheter Sets	See MDR 759428
10F Tesio, Duo-Jet II, Chronic Twinline Long-Term Hemodialysis Catheter Sets	See MDR 759438
Split Cath Long-Term Hemodialysis Catheter Sets	See MDR 759431
Split Stream Long-Term Hemodialysis Catheter Sets	See MDR 759433
6.5F Tesio Long-Term Hemodialysis Catheter Sets	See MDR 759439
Canaud Long-Term Hemodialysis Catheter Sets	See MDR 759442
Hemo-Cath LT Long-Term Hemodialysis Catheter Sets	See MDR 759436

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

Device(s)	Risk Classification
Vascular Access Guidewires, Needles, Tunnelers, Adaptors, Introducers, Dilators	Class IIa
Catheter Accessories	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
2022-11-08	3277844	Issued.
Current	3808456	Supplemented – Addition of Split-Cath Long-Term Hemodialysis Catheter Sets, Split Stream Long-Term Hemodialysis Catheter Sets, 6.5F Tesio Long-Term Hemodialysis Catheter Sets, Canaud Long-Term Hemodialysis Catheter Sets, and Hemo-Cath LT Long-Term Hemodialysis Catheter Sets devices.

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