EU Quality Management System Certificate

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

MDR 736225 R000

Manufacturer: Teleflex Medical

Address:
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Single Registration Number: IE-MF-000015868

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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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: **2021-08-20**

Current Issue Date: **2024-03-11**

Starting Validity Date: **2024-03-11**

Expiry Date: **2026-08-19**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Ureterocutaneostomy Catheters	Intended for the routine drainage of urine through a ureterocutaneous stoma site.
Tracheostomy Tubes	Intended for cannulation of tracheostomy patients with an existing tracheostoma.
Tracheostomy Inner Cannulas	Intended for cannulation of existing tracheotomised patients through an existing tracheostoma.

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

Device(s)	Risk Classification
Specimen Retrieval Bags	Class IIa – Non-Implantable
Urological Guidewires	Class IIa – Non-Implantable
Kidney Stone Extractors	Class IIa – Non-Implantable
Temperature Sensors	Class IIa – Non-Implantable
Percutaneous Nephrostomy Catheter Sets	Class IIa – Non-Implantable
Tracheostomy Tubes	Class IIa – Non-Implantable
Tracheostomy Tube Accessories	Class Is
Bladder Catheters	Class Is
Ureteral Catheter Accessories	Class Is
Ureteral Dilators	Class Is
Neck Bands	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
2021-08-20	3290676	Issued.
2021-08-30	3290676	Amended - correction of the manufacturer address.
2021-10-25	3541853	Amended - correction to current issue date.
2022-03-01	3621589	Amended – addition of sterilisation method to subcontractor.
2023-06-20	3564000	Supplemented – Addition of Ureteral Catheter Accessories, Ureteral Dilators, and Neck Bands Restricted – Removal of Intubation Device Amended – Administrative update to certificate history
2023-11-02	30006521	Supplemented – Addition of Ureterocutaneostomy Catheters, Kidney Stone Extractors, Class IIa Tracheostomy Tubes
Current	30054827	Supplemented – Addition of Specimen Retrieval Bags, Urological Guidewires, Temperature Sensors, Percutaneous Nephrostomy Catheter Sets, Tracheostomy Inner Cannulas, Class IIb Tracheostomy Tubes, Tracheostomy Tube Accessories Amended – Administrative update to certificate history

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