CERTIFICATE

Number: 3821543

The management system of:

Freudenberg Medical, LLC

2301 Centennial Blvd
Jeffersonville, IN 47130-8975
United States Of America

Manufacturer Facility Identifier F003041

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:
Design and manufacture of specialty catheters and guidewires; manufacture of catheters, introducers, biopsy needles, stents, syringes, cannulas, electrosurgical and coagulation devices, radiographic markers, and endoscopic traction devices for the cardiovascular, pulmonary, peripheral vascular, urological, flexible endoscopy, gastrointestinal, bariatric, ophthalmic, neurovascular and interventional radiology medical device industry.

Certificate expiry date: 19 September 2025
Certificate effective date: 20 September 2022
Certified since: 19 September 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM