European Declaration of Conformity to the Medical Device Directive, 93/42/EEC

Manufacturer: Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095 USA

EU Representative: Merit Medical Ireland, Ltd.
Parkmore Business Park West
Galway, Ireland

Product(s)/Product Category(ies): Maestro Microcatheters

Model(s) / Device(s) Catalog / Model Numbers: For Catalog Number listing refer to electronically generated Oracle CE Mark Report

Classification/Rule: Class IIa; Rule 7 according to Annex IX of the MDD

Conformity/Assessment Route: Annex II Section 3.2 of EC Directive 93/42/EEC

Global Medical Device Nomenclature Code: 10691 Intravascular Microflow Catheter

Universal Medical Device Nomenclature System Number: N/A

We declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices, as amended in accordance with 2007/47/EC. This declaration is supported by the Quality System Certificate No. FM 534441 issued originally 05 September 2008 by BSI Management Systems. All supporting documentation is retained at the premises of the manufacturer.

Notified Body: BSI
Notified Body Number 2797

Digitally signed by Ostapciuc Alexandr
Date: 2023.07.08 14:06:11 EEST
Reason: MoldSign Signature
Location: Moldova

EC Certificate(s): 541900
Date of Issue: 3 October 2008

Signature: DocuSigned by: Glenn Norton D093B07B86D2456...

Date: 04 January 2021 | 4:14 PM MST

Glenn Norton
Vice President, Regulatory Affairs
Approvals maybe acquired per 20-MEMO-0097