

## **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. 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:** 

Notified Body Number 2797

EC Certificate(s):

541900

Date of Issue:

3 October 2008

Signature:

Glenn Norton

Vice President, Regulatory Affairs

Date: 19 November 2019