MERIT MEDICAL

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): ASAP100 Aspiration Catheter Kit, ASAPLP Aspiration Catheter Kit

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

Classification/Rule: Class III; Rule 6 according to Annex IX of the MDD

Digitally signed by Cucere
Date: 2019.09.17 12:14:59
Reason: MoldSign Signatu
Location: Moldova

Conformity/Assessment Route: Annex II, Section 4 of EC Directive 93/42/EEC

Global Medical Device Nomenclature Code: 58977 Basic intravenous administration set

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:
BSI
Notified Body Number 0086

EC Certificate(s):	541900	**DEC Certificate(s):**	561259
Date of first Issue:	3 Oct 2008	**Date of first Issue:**	7 Jul 2010

Signature: John C. Knorpp
Chief Regulatory Affairs Officer

Date: 4 Jan. '17