



**European Declaration of Conformity
to the Medical Device Directive, 93/42/EEC
and to the Council Directive 2011/65/EU (“RoHS 2”)**

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): Manifolds, Manifold with Integrated Transducer, Stopcocks, Flow Switch

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

Classification/Rule: Class IIa; Rule 2 according to Annex IX of the MDD
Class IIa non-sterile, Rule 2 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:** 35375 Stopcocks

**Universal Medical Device
Nomenclature System Number:** 16387 Manifolds, Stopcock


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 2007/42/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.

We declare that the Manifold with Integrated Transducer meet the provisions of the Council Directive 2011/65/EU (“RoHS 2”).

Notified Body: BSI
Notified Body Number 2797

EC Certificate(s): 541900

Date of Issue: 3 October 2008

Signature: 
Glenn Norton
Vice President, Regulatory Affairs

Date: 28 May 2020