



**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):** High Pressure Tubing and Pressure Monitoring Tubing  
**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

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

**Global Medical Device Nomenclature Code:** 44685 Radiographic procedure tubing

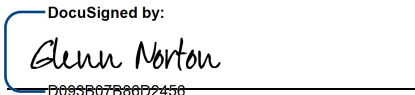
**Universal Medical Device Nomenclature System Number:** 14238 Tubing

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

**EC Certificate(s):** 541900

**Date of Issue:** 3 October 2008

**Signature:**   
Glenn Norton  
Vice President, Regulatory Affairs

**Date:** 26 May 2021 | 2:10 PM MDT

Approvals may be acquired per 20-Memo-0097