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): Syringes

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

Classification/Rule: Class I Sterile Measuring; Rule 2 according to Annex IX of the MDD
Class I Non-sterile Measuring, 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:

47017	General Purpose Syringe, Single Use
15286	Angiographic Syringe

Universal Medical Device Nomenclature System Number: 13929 Syringes

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): CE 541900
Date of Issue: 3 October 2008

Signature: DocuSigned by: Glenn Norton D093B07B86D2456... **Date:** 19 November 2020 | 12:13 PM MST

Glenn Norton
Vice President, Regulatory Affairs
(Approval may be acquired per 20-MeMO-0097)