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):	Inflation Devices – Analog Inflation Devices
Model(s) / Device(s) Catalog / Model Numbers:	For Catalog Number listing refer to electronically generated Oracle CE Mark Report
Classification/Rule:	Class I Sterile; Rule 1 according to Annex IX of the MDD for Inflation Devices Class IIa; Rule 2 according to Annex IX of the MDD for Inflation devices with MAP™ (Merit Angioplasty Packs)
Conformity/Assessment Route:	Annex II, Section 3.2 of EC Directive 93/42/EEC
Global Medical Device Nomenclature Code:	17541 36079
Universal Medical Device Nomenclature System Number:	17541 36079

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 2797
EC Certificate(s):	CE 541900
Date of Issue:	03 October 2008

Signature: Tony Keaveney

Tony Keaveney
Executive Vice President, Regulatory Affairs

Date: 21 MAR 2019.