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):
Custom Kits (Refer to table below.); Bonded Devices ("PHT" codes); and Merit Molded Caps, Covers, and Connectors

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

Classification/Rule:
Class I, IIa, IIb; the following may be applicable: Rule 1, Rule 2, Rule 4, Rule 5, Rule 6, Rule 7, Rule 10, Rule according to Annex IX of the MDD

Conformity/Assessment Route:
Article 11 of EC Directive 93/42/EEC

Global Medical Device Nomenclature Code:

Kit Type	GMDN	GMDN Term
K04	44685	Radiographic procedure tubing
K05	17541	Catheter-balloon inflator, single-use
K08	58977	Basic intravenous administration set
K09	47258	Contrast medium injection system manifold kit
K10	11301	Closed-wound drainage reservoir
K11	45275	Blood pressure transducer set
K12	33961	General/Plastic surgical procedure kit, non-medicated, single use
K14	61354	Peritoneal dialysis catheter introduction set
K15	58865	Vascular catheter introduction kit, non-steerable
K16	10691	Intravascular microflow catheter
K18	58865	Vascular catheter introduction kit, non-steerable
K21	58865	Vascular catheter introduction kit, non-steerable

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.

We declare that the above mentioned product(s) meet the provisions of the Council Directive 2011/65/EU ("RoHS 2").

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:** 13 May 2021 | 5:23 PM MDT

Glenn Norton
Vice President, Regulatory Affairs

Approvals maybe acquired per 20-MEMO-0097.