EC DESIGN-EXAMINATION CERTIFICATE

Number: 3809162DE02

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:
Merit Medical Systems Inc
1600 West Merit Parkway
South Jordan, UT 84095
United States Of America

For the product

Transseptal Devices

Documents, that form the basis of this certificate:

Certification Notice 3827127CN, initially dated 13 March 2020
CE Marking of Conformity 3809162CE01
Addendum, initially dated 20 August 2012

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until:	1 July 2023
Issued for the first time:	20 August 2012
Revised:	13 March 2020
Reissued:	1 July 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 3809162DE02

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Transseptal Devices

Issued to:

Merit Medical Systems Inc
1600 West Merit Parkway
South Jordan, UT 84095
United States Of America

This certificate covers the following product(s):

Transseptal Needle Kit (GMDN:47248)
- Tip Gage: 21-22 ga
- Length: 56-98 cm
- Curve: 50-86°

Fixed Curve Braided Transseptal Sheath Introducer (GMDN:47247)
- Diameter : 8.5 F
- Length: 60 - 101.5 cm
- Curve: 15 - 180º and multiplanar (ML1 and ML2)

Initial date: 20 August 2012
Revision date: 13 March 2020

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