



EC DECLARATION OF CONFORMITY

(Following the provisions of the medical devices directive 93/42/EEC)

No. DD-002, Rev. AL

Date: 01-JUNE-2021

We

Manufacturer
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095 USA

EU Authorized Representative
Merit Medical Ireland
Parkmore Business Park West
Galway, Ireland

Declare under our sole responsibility that the class III device:

TRANSSEPTAL DEVICES

(needles, introducer sets, guidewires and accessories)

<Definition as written in the GMDNS code>

Ref. : see addendum

Merit Medical Product Family	GMDN Code	Term Definition
Transseptal needle	47248	Cardiac transeptal needle A device designed to puncture the interatrial septum during a transeptal catheterization procedure to gain left heart access typically to facilitate fluid aspiration and injection/infusion, blood sampling, and pressure monitoring. It is typically a long, thin stainless steel tube that is curved and pointed at the distal end, usually having a hub with a stopcock and orientation indicators at the proximal end. It may include a stylet for support during handling. This is a single-use device.
Fixed Curve Braided Transseptal Sheath Kit	47247	Transseptal access system An assembly of devices used to puncture the interatrial septum during a transeptal catheterization procedure and to create a conduit for the introduction of various cardiovascular catheters into the left side of the heart. It typically includes a guidewire to facilitate the advancement of the assembled device, a sheath as the conduit, a dilator with a curved distal portion to accommodate positioning against the atrial septum, a luminal needle to create the puncture (e.g., for fluid aspiration and injection/infusion, blood sampling, pressure monitoring), and a stylet to support the needle during handling. This is a single-use device.

Classification rule (93/42/EC Annex IX) : **6 (six)**

To which this declaration relates is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it.

This conformity is based on the following elements :

- Information included in the documents :
Design History File Ref./ réf. : **DD-002**, of the product to which this declaration relates.
- EC certificate: approval of full quality assurance system (annex II of the medical devices directive 93/42 EEC) delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344 on 12-SEP-2012 Certificate N° 3809162CE01

EN ISO 13485:2016 – certificate number 3820098
 ISO 13485:2016 MDSAP - certificate number 3830098
 93/42/EEC Annex II, 4 certificate number 3809162DE02
 93/42/EEC Annex II certificate number 3809162CE01

01 June 2021 | 1:36 PM MDT

Date

DocuSigned by:

Glenn Norton

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Glenn Norton

Vice President, Regulatory Affairs

Approvals may be acquired per 20-MEMO-0097

This EC declaration of conformity supersedes the previous declaration dated 24-MAY-2021).



ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 01-JUNE-2021

	Merit Medical Part No.	Catalog No. (Model No.)	Description	Date CE first applied
FND-019-XX Class III	FND-019-00	FND-019-00	19 G x 56cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-019-01	FND-019-01	18 G x 71 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-019-02	FND-019-02	18 G x 71 cm Curve III, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-019-03	FND-019-03	18 G x 89 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-019-04	FND-019-04	18 G x 89 cm Curve III, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-019-05	FND-019-05	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-019-06	FND-019-06	18 G x 98 cm Curve III, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-019-07	FND-019-07	18 G x 82cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
FND-019-XX/A Class III	FND-019-00/A	FND-019-00	19 G x 56cm Curve I, Transseptal Needle Kit & Stylet	20-DEC-2019
	FND-019-01/A	FND-019-01	18 G x 71 cm Curve I, Transseptal Needle Kit & Stylet	20-DEC-2019
	FND-019-02/A	FND-019-02	18 G x 71 cm Curve III, Transseptal Needle Kit & Stylet	20-DEC-2019
	FND-019-03/A	FND-019-03	18 G x 89 cm Curve I, Transseptal Needle Kit & Stylet	20-DEC-2019
	FND-019-04/A	FND-019-04	18 G x 89 cm Curve III, Transseptal Needle Kit & Stylet	20-DEC-2019
	FND-019-05/A	FND-019-05	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	20-DEC-2019
	FND-019-06/A	FND-019-06	18 G x 98 cm Curve III, Transseptal Needle Kit & Stylet	20-DEC-2019
FND-019-XX/B Class III	FND-019-01/B	FND-019-01	18 G x 71 cm Curve I, Transseptal Needle Kit & Stylet	21-May-2020
	FND-019-02/B	FND-019-02	18 G x 71 cm Curve III, Transseptal Needle Kit & Stylet	21-May-2020
	FND-019-03/B	FND-019-03	18 G x 89 cm Curve I, Transseptal Needle Kit & Stylet	21-May-2020
	FND-019-04/B	FND-019-04	18 G x 89 cm Curve III, Transseptal Needle Kit & Stylet	21-May-2020
	FND-019-05/B	FND-019-05	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	21-May-2020
	FND-019-06/B	FND-019-06	18 G x 98 cm Curve III, Transseptal Needle Kit & Stylet	21-May-2020
FND-020-XX Class III	FND-020-00	FND01900	19 G x 56cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-01	FND01901	18 G x 71 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-02	FND01902	18 G x 71 cm Curve III, Transseptal Needle Kit & Stylet	12-SEP-2012



	FND-020-03	FND01903	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-05	FND01905	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-06	FND01906	18 G x 89 cm Curve III, Transseptal Needle Kit & Stylet	12-SEP-2012
FND-020-XX/A Class III	FND-020-00/A	FND01900	19 G x 56cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-01/A	FND01901	18 G x 71 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-02/A	FND01902	18 G x 71 cm Curve III, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-03/A	FND01903	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-05/A	FND01905	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	12-SEP-2012
	FND-020-06/A	FND01906	18 G x 89 cm Curve III, Transseptal Needle Kit & Stylet	12-SEP-2012
FND-020-XX/B Class III	FND-020-01/B	FND01901	18 G x 71 cm Curve I, Transseptal Needle Kit & Stylet	20-JAN-2021
	FND-020-02/B	FND01902	18 G x 71 cm Curve III, Transseptal Needle Kit & Stylet	20-JAN-2021
	FND-020-03/B	FND01903	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	20-JAN-2021
	FND-020-05/B	FND01905	18 G x 98 cm Curve I, Transseptal Needle Kit & Stylet	20-JAN-2021
	FND-020-06/B	FND01906	18 G x 89 cm Curve III, Transseptal Needle Kit & Stylet	20-JAN-2021
FND-026-XX/A Class III	FND-026-01/A	FND02601	CardiaGuide™ Transseptal Needle Kit & Stylet. 18G.71 cm.50°	12-SEP-2012
	FND-026-02/A	FND02602	CardiaGuide™ Transseptal Needle Kit & Stylet. 18G.71 cm.86°	12-SEP-2012
	FND-026-03/A	FND02603	CardiaGuide™ Transseptal Needle Kit & Stylet. 18G.89 cm.50°	12-SEP-2012
	FND-026-05/A	FND02605	CardiaGuide™ Transseptal Needle Kit & Stylet. 18G.98 cm.50°	12-SEP-2012
	FND-026-06/A	FND02606	CardiaGuide™ Transseptal Needle Kit & Stylet. 18G.98 cm.86°	12-SEP-2012
FND-025-XX Class III	FND-025-01	M004TSX100	TSX™ Transseptal Needle 18GA, 71cm, Std (50°) Crv	12-SEP-2012
	FND-025-02	M004TSX200	TSX™ Transseptal Needle 18GA, 71cm, Lrg (86°) Crv	12-SEP-2012
	FND-025-03	M004TSX300	TSX™ Transseptal Needle 18GA, 89cm, Std (50°) Crv	12-SEP-2012
	FND-025-04	M004TSX400	TSX™ Transseptal Needle 18GA, 89cm, Lrg (86°) Crv	12-SEP-2012
	FND-025-05	M004TSX500	TSX™ Transseptal Needle 18GA, 98cm, Std (50°) Crv	12-SEP-2012
	FND-025-06	M004TSX600	TSX™ Transseptal Needle 18GA, 98cm, Lrg (86°) Crv	12-SEP-2012
FND-025-XX/A Class III	FND-025-01/A	M004TSXNEEDLE100	TSX™ Transseptal Needle 18GA, 71cm, Std (50°) Crv	12-SEP-2012



	FND-025-02/A	M004TSXNEEDLE200	TSX™ Transseptal Needle 18GA, 71cm, Lrg (86°) Crv	12-SEP-2012
	FND-025-03/A	M004TSXNEEDLE300	TSX™ Transseptal Needle 18GA, 89cm, Std (50°) Crv	12-SEP-2012
	FND-025-04/A	M004TSXNEEDLE400	TSX™ Transseptal Needle 18GA, 89cm, Lrg (86°) Crv	12-SEP-2012
	FND-025-05/A	M004TSXNEEDLE500	TSX™ Transseptal Needle 18GA, 98cm, Std (50°) Crv	12-SEP-2012
	FND-025-06/A	M004TSXNEEDLE600	TSX™ Transseptal Needle 18GA, 98cm, Lrg (86°) Crv	12-SEP-2012
FCL-160-xx Class III	FCL-160-00	FCL-160-00	8.5F x 60 cm Heartspan Fixed Curve Kit – 15 degree	12-SEP-2012
	FCL-160-01	FCL-160-01	8.5F x 60 cm Heartspan Fixed Curve Kit – 30 degree	12-SEP-2012
	FCL-160-02	FCL-160-02	8.5F x 60 cm Heartspan Fixed Curve Kit – 55 degree	12-SEP-2012
	FCL-160-03	FCL-160-03	8.5F x 60 cm Heartspan Fixed Curve Kit – 120 S degree	12-SEP-2012
	FCL-160-04	FCL-160-04	8.5F x 60 cm Heartspan Fixed Curve Kit – 120 L degree	12-SEP-2012
	FCL-160-05	FCL-160-05	8.5F x 60 cm Heartspan Fixed Curve Kit – 150 I degree	12-SEP-2012
	FCL-160-06	FCL-160-06	8.5F x 79.4 cm Heartspan Fixed Curve Kit – 15 degree	12-SEP-2012
	FCL-160-07	FCL-160-07	8.5F x 79.4 cm Heartspan Fixed Curve Kit – 55 degree	12-SEP-2012
	FCL-160-08	FCL-160-08	8.5F x 79.4 cm Heartspan Fixed Curve Kit – 90 degree	12-SEP-2012
	FCL-160-09	FCL-160-09	8.5F x 79.4 cm Heartspan Fixed Curve Kit – 120 L degree	12-SEP-2012
	FCL-160-10	FCL-160-10	8.5F x 101.5 cm Heartspan Fixed Curve Kit – 55 degree	12-SEP-2012
FCL-160-xx/A Class III	FCL-160-00/A	FCL-160-00	8.5F x 60 cm Heartspan Fixed Curve Kit – 15 degree	16-MAR-2020
	FCL-160-01/A	FCL-160-01	8.5F x 60 cm Heartspan Fixed Curve Kit – 30 degree	16-MAR-2020
	FCL-160-02/A	FCL-160-02	8.5F x 60 cm Heartspan Fixed Curve Kit – 55 degree	16-MAR-2020
	FCL-160-03/A	FCL-160-03	8.5F x 60 cm Heartspan Fixed Curve Kit – 120 S degree	16-MAR-2020
	FCL-160-04/A	FCL-160-04	8.5F x 60 cm Heartspan Fixed Curve Kit – 120 L degree	16-MAR-2020
	FCL-160-05/A	FCL-160-05	8.5F x 60 cm Heartspan Fixed Curve Kit – 150 I degree	16-MAR-2020
	FCL-160-06/A	FCL-160-06	8.5F x 79.4 cm Heartspan Fixed Curve Kit – 15 degree	16-MAR-2020
	FCL-160-07/A	FCL-160-07	8.5F x 79.4 cm Heartspan Fixed Curve Kit – 55 degree	16-MAR-2020
	FCL-160-08/A	FCL-160-08	8.5F x 79.4 cm Heartspan Fixed Curve Kit – 90 degree	16-MAR-2020



	FCL-160-09/A	FCL-160-09	8.5F x 79.4 cm Heartspan Fixed Curve Kit – 120 L degree	16-MAR-2020
	FCL-160-10/A	FCL-160-10	8.5F x 101.5 cm Heartspan Fixed Curve Kit – 55 degree	16-MAR-2020
FCL-191-xx Class III	FCL-191-00	M004TSXFS100	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60cm, 15°Crv	12-SEP-2012
	FCL-191-01	M004TSXFS200	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60 cm, 30°Crv	12-SEP-2012
	FCL-191-02	M004TSXFS300	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60cm, 55°Crv	12-SEP-2012
	FCL-191-03	M004TSXFS400	TSX™ Fixed Curve Transseptal Sheath 8.5F 60cm, 120S°Crv	12-SEP-2012
	FCL-191-04	M004TSXFS500	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60cm, 120L°Crv	12-SEP-2012
	FCL-191-05	M004TSXFS600	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60cm, 150i°Crv	12-SEP-2012
	FCL-191-06	M004TSXFS700	TSX™ Fixed Curve Transseptal Sheath 8.5F, 79.4cm, 15°Crv	12-SEP-2012
	FCL-191-07	M004TSXFS800	TSX™ Fixed Curve Transseptal Sheath 8.5F, 79.4cm, 55°Crv	12-SEP-2012
	FCL-191-08	M004TSXFS900	TSX™ Fixed Curve Transseptal Sheath 8.5F, 79.4cm, 90°Crv	12-SEP-2012
	FCL-191-09	M004TSXFS1100	TSX™ Fixed Curve Transseptal Sheath 8.5F, 79.4cm, 120L°Crv	12-SEP-2012
	FCL-191-10	M004TSXFS1200	TSX™ Fixed Curve Transseptal Sheath 8.5F, 101.5cm, 55°Crv	12-SEP-2012
FCL-191-xx/A Class III	FCL-191-00/A	M004TSXSHEATH100	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60cm, 15°Crv	16-MAR-2020
	FCL-191-01/A	M004TSXSHEATH200	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60 cm, 30°Crv	16-MAR-2020
	FCL-191-02/A	M004TSXSHEATH300	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60cm, 55°Crv	16-MAR-2020
	FCL-191-03/A	M004TSXSHEATH400	TSX™ Fixed Curve Transseptal Sheath 8.5F 60cm, 120S°Crv	16-MAR-2020
	FCL-191-04/A	M004TSXSHEATH500	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60cm, 120L°Crv	16-MAR-2020
	FCL-191-05/A	M004TSXSHEATH600	TSX™ Fixed Curve Transseptal Sheath 8.5F, 60cm, 150i°Crv	16-MAR-2020
	FCL-191-06/A	M004TSXSHEATH700	TSX™ Fixed Curve Transseptal Sheath 8.5F, 79.4cm, 15°Crv	16-MAR-2020
	FCL-191-07/A	M004TSXSHEATH800	TSX™ Fixed Curve Transseptal Sheath 8.5F, 79.4cm, 55°Crv	16-MAR-2020
	FCL-191-08/A	M004TSXSHEATH900	TSX™ Fixed Curve Transseptal Sheath 8.5F, 79.4cm, 90°Crv	16-MAR-2020
	FCL-191-09/A	M004TSXSHEATH1100	TSX™ Fixed Curve Transseptal Sheath 8.5F, 79.4cm, 120L°Crv	16-MAR-2020



FCL-196-xx Class III	FCL-196-01	FCL16001	8.5F x 60 cm HeartSpan® Fixed Curve Braided Transseptal Sheath – 30 degree	12-SEP-2012
	FCL-196-02	FCL16002	8.5F x 60 cm HeartSpan® Fixed Curve Braided Transseptal Sheath – 55 degree	12-SEP-2012
	FCL-196-07	FCL16007	8.5F x 79.4 cm HeartSpan® Fixed Curve Braided Transseptal Sheath – 55 degree	12-SEP-2012
FCL-196-xx/A Class III	FCL-196-01/A	FCL16001	8.5F x 60 cm HeartSpan® Fixed Curve Braided Transseptal Sheath – 30 degree	16-MAR-2020
	FCL-196-02/A	FCL16002	8.5F x 60 cm HeartSpan® Fixed Curve Braided Transseptal Sheath – 55 degree	16-MAR-2020
	FCL-196-07/A	FCL16007	8.5F x 79.4 cm HeartSpan® Fixed Curve Braided Transseptal Sheath – 55 degree	16-MAR-2020
FCL-201-xx/A Class III	FCL-201-00/A	FCL20100	CardiaGuide™.Fixed Curve Braided Transseptal Sheath Kit.8.5F.63 cm.50°	03-DEC-2020
	FCL-201-01/A	FCL20101	CardiaGuide™.Fixed Curve Braided Transseptal Sheath Kit.8.5F.63 cm.ML1	03-DEC-2020
	FCL-201-02/A	FCL20102	CardiaGuide™.Fixed Curve Braided Transseptal Sheath Kit.8.5F.81 cm.50°	03-DEC-2020
	FCL-201-03/A	FCL20103	CardiaGuide™.Fixed Curve Braided Transseptal Sheath Kit.8.5F.81 cm.ML1	03-DEC-2020
FCB85xxxxx Class III	FCB856345	FCB856345	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 45° curve, 63cm	12-JUL-2016
	FCB858145	FCB858145	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 45° curve, 81cm	12-JUL-2016
	FCB8563MR0	FCB8563MR0	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 50° curve, 63cm	31-JAN-2019
	FCB8581MR0	FCB8581MR0	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 50° curve, 81cm	31-JAN-2019
	FCB8563ML0	FCB8563ML0	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 50° curve, 63cm	12-JUL-2016
	FCB8581ML0	FCB8581ML0	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 50° curve, 81cm	12-JUL-2016
	FCB856390	FCB856390	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 90° curve, 63cm	12-JUL-2016
	FCB858190	FCB858190	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 90° curve, 81cm	12-JUL-2016
	FCB8563120	FCB8563120	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 120° curve, 63cm	12-JUL-2016
	FCB8581120	FCB8581120	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 120° curve, 81cm	12-JUL-2016
	FCB8563135	FCB8563135	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 135° curve, 63cm	12-JUL-2016
	FCB8581135	FCB8581135	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 135° curve, 81cm	12-JUL-2016
	FCB8563150	FCB8563150	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 150° curve, 63cm	12-JUL-2016
	FCB8581150	FCB8581150	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 150° curve, 81cm	12-JUL-2016
	FCB8563ML1	FCB8563ML1	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, Multiplanar curve I, 63cm	12-JUL-2016



	FCB8581ML1	FCB8581ML1	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, Multiplanar curve 1, 81cm	12-JUL-2016
	FCB8563ML2	FCB8563ML2	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, Multiplanar curve 2, 63cm	11-MAR-2019
	FCB8581ML2	FCB8581ML2	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, Multiplanar curve 2, 81cm	11-MAR-2019
	FCB8560MP18	FCB8560MP18	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 180° curve, 60cm	03-JUL-2019
	FCB8560MP28	FCB8560MP28	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 180° curve, 60cm	03-JUL-2019
	FCB8561MUL	FCB8561MUL	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 180° curve, 61cm	03-JUL-2019
FCB85xxxx/A Class III	FCB856345/A	FCB856345	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 45° curve, 63cm	16-MAR-2020
	FCB858145/A	FCB858145	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 45° curve, 81cm	16-MAR-2020
	FCB8563MR0/A	FCB8563MR0	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 50° curve, 63cm	16-MAR-2020
	FCB8581MR0/A	FCB8581MR0	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 50° curve, 81cm	16-MAR-2020
	FCB8563ML0/A	FCB8563ML0	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 50° curve, 63cm	16-MAR-2020
	FCB8581ML0/A	FCB8581ML0	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 50° curve, 81cm	16-MAR-2020
	FCB856390/A	FCB856390	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 90° curve, 63cm	16-MAR-2020
	FCB858190/A	FCB858190	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 90° curve, 81cm	16-MAR-2020
	FCB8563120/A	FCB8563120	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 120° curve, 63cm	16-MAR-2020
	FCB8581120/A	FCB8581120	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 120° curve, 81cm	16-MAR-2020
	FCB8563135/A	FCB8563135	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 135° curve, 63cm	16-MAR-2020
	FCB8581135/A	FCB8581135	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 135° curve, 81cm	16-MAR-2020
	FCB8563150/A	FCB8563150	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 150° curve, 63cm	16-MAR-2020
	FCB8581150/A	FCB8581150	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 150° curve, 81cm	16-MAR-2020
	FCB8563ML1/A	FCB8563ML1	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, Multiplanar curve 1, 63cm	16-MAR-2020
	FCB8581ML1/A	FCB8581ML1	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, Multiplanar curve 1, 81cm	16-MAR-2020
	FCB8563ML2/A	FCB8563ML2	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, Multiplanar curve 2, 63cm	16-MAR-2020
	FCB8581ML2/A	FCB8581ML2	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, Multiplanar curve 2, 81cm	16-MAR-2020
	FCB8560MP18/A	FCB8560MP18	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 180° curve, 60cm	16-MAR-2020



FCB8560MP28/A	FCB8560MP28	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 180° curve, 60cm	16-MAR-2020
FCB8561MUL/A	FCB8561MUL	HeartSpan® Fixed Curve Braided Transseptal Sheath, 8.5F, 180° curve, 61cm	16-MAR-2020



Revision History :

<u>Revision</u>	<u>Date</u>	<u>Change</u>																																			
E	02-NOV-2011	Added PNs : FND-019-04, FND-019-05, FND-019-06																																			
F	22-DEC-2011	Added : FCL-173-xx HeartSpan series																																			
G	07-FEB-2012	Added : FCL-176-xx EZ Cross series																																			
H	08-FEB-2012	Added : FCL-176-00 (inadvertent omission from Rev. G)																																			
I	25-APR-2012	Updated format to new DOC template																																			
J	20-JUN-2012	Added : FND-022-xx series																																			
K	13-SEP-2012	<p>Convert from TUV-Nort to DEKRA as NB and revise all associated refereneces. Remove obsolete product codes :</p> <table border="1"> <tbody> <tr> <td>XD-1779-00</td> <td>XD-1779-01</td> <td>XD-1779-02</td> <td>XD-1779-03</td> <td>XD-1779-04</td> </tr> <tr> <td>XD-1779-05</td> <td>XD-1779-06</td> <td>XD-2032-02</td> <td>XD-2032-03</td> <td>XD-2032-04</td> </tr> <tr> <td>XD-2032-05</td> <td>XD-2032-07</td> <td>XD-2032-08</td> <td>XD-2032-09</td> <td>XD-2032-10</td> </tr> <tr> <td>XD-2032-11</td> <td>XD-2101-00</td> <td>XD-2101-01</td> <td>XD-2101-02</td> <td>XD-2101-03</td> </tr> <tr> <td>XD-2101-04</td> <td>XD-2101-05</td> <td>XD-2101-06</td> <td>XD-2101-07</td> <td>XD-2101-08</td> </tr> <tr> <td>FND-017-00</td> <td>FND-015-00</td> <td>FND-015-01</td> <td>FND-015-02</td> <td>FND-016-03</td> </tr> <tr> <td>FND-016-02</td> <td>FND-017-01</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	XD-1779-00	XD-1779-01	XD-1779-02	XD-1779-03	XD-1779-04	XD-1779-05	XD-1779-06	XD-2032-02	XD-2032-03	XD-2032-04	XD-2032-05	XD-2032-07	XD-2032-08	XD-2032-09	XD-2032-10	XD-2032-11	XD-2101-00	XD-2101-01	XD-2101-02	XD-2101-03	XD-2101-04	XD-2101-05	XD-2101-06	XD-2101-07	XD-2101-08	FND-017-00	FND-015-00	FND-015-01	FND-015-02	FND-016-03	FND-016-02	FND-017-01			
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L	30-NOV-2012	<p>Added :</p> <p>FND-015-01 FND-015-02 (XD-1779-05) FND-015-04 FND-015-05 FND-015-06</p> <p>FND-015-03 revise description from "18 g x 71 cm trans. Needle kit – adult standard curve long" to "18g x 89cm Transseptal Needle Kit 50 degree curve"</p>																																			
M	01-MAR-2013	<p>Remove references of GE Healthcare and replace with Merit Medical Revise the following</p> <table border="1"> <thead> <tr> <th>Manufacturer</th> <th>Removed</th> <th>Replaced With</th> </tr> </thead> <tbody> <tr> <td></td> <td>Thomas Medical Products A GE Healthcare Company</td> <td>Merit Medical Systems, Inc.</td> </tr> <tr> <th>EU Authorized Representative</th> <td>GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France</td> <td>Merit Medical Ireland Parkmore Business Park West Galway, Ireland</td> </tr> </tbody> </table>	Manufacturer	Removed	Replaced With		Thomas Medical Products A GE Healthcare Company	Merit Medical Systems, Inc.	EU Authorized Representative	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France	Merit Medical Ireland Parkmore Business Park West Galway, Ireland																										
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N	14-MAR-2013	Remove reference to Thomas Medical Products, Inc.																																			
O	17-APR-2013	Replace « Peter Rapp, VP Operations » with Bob O’Hara, Director, Quality Systems																																			
P	22-OCT-2013	Revise classification of Fixed Curve Kit (FCL-160-XX, FCL-173-XX & FCL-176-XX) from Class IIA to Class III																																			
Q	05-JUN-2014	<p>Add the following PNs</p> <table border="1"> <tbody> <tr> <td>FCL-191-00</td> <td>FCL-191-01</td> <td>FCL-191-02</td> <td>FCL-191-03</td> <td>FCL-191-04</td> </tr> <tr> <td>FCL-191-05</td> <td>FCL-191-06</td> <td>FCL-191-07</td> <td>FCL-191-08</td> <td>FCL-191-09</td> </tr> <tr> <td>FCL-191-10</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>FND-025-01</td> <td>FND-025-02</td> <td>FND-025-03</td> <td>FND-025-04</td> <td>FND-025-05</td> </tr> <tr> <td>FND-025-06</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	FCL-191-00	FCL-191-01	FCL-191-02	FCL-191-03	FCL-191-04	FCL-191-05	FCL-191-06	FCL-191-07	FCL-191-08	FCL-191-09	FCL-191-10					FND-025-01	FND-025-02	FND-025-03	FND-025-04	FND-025-05	FND-025-06														
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R	17-JUL-2014	<p>Revise description for FND-025-XX from « TSX Needle... » to « TSX™ Transseptal Needle... » Revise description for FCL-191-XX from »TSXFS... » to « TSX™ Fixed Curve Transseptal Sheath... «</p>																																			
S	05-DEC-2014	<p>Revise UMDNS to GMDN</p> <p>From</p> <table border="1"> <thead> <tr> <th>Merit Medical Product Family</th> <th>UMDNS code</th> <th>Term Definition</th> </tr> </thead> <tbody> <tr> <td>Transseptal needle</td> <td>12 738 15 234</td> <td>Needles; cardiac Needles; other</td> </tr> </tbody> </table>	Merit Medical Product Family	UMDNS code	Term Definition	Transseptal needle	12 738 15 234	Needles; cardiac Needles; other																													
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T	26-JAN-2015	Replace PN : FND-021-00 with FND-019-07														
U	16-JUN-2015	Add PN FND-020-05 & FND-020-06														
V	04-MAY-2016	<p>Update catalog numbers :</p> <table> <tr> <td>From</td> <td>To</td> </tr> <tr> <td>M004TSXN100</td> <td>M004TSX100</td> </tr> <tr> <td>M004TSXN200</td> <td>M004TSX200</td> </tr> <tr> <td>M004TSXN300</td> <td>M004TSX300</td> </tr> <tr> <td>M004TSXN400</td> <td>M004TSX400</td> </tr> <tr> <td>M004TSXN500</td> <td>M004TSX500</td> </tr> <tr> <td>M004TSXN600</td> <td>M004TSX600</td> </tr> </table> <p>Replace signature from Bob O'Hara to Tim Stoudt</p>	From	To	M004TSXN100	M004TSX100	M004TSXN200	M004TSX200	M004TSXN300	M004TSX300	M004TSXN400	M004TSX400	M004TSXN500	M004TSX500	M004TSXN600	M004TSX600
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W	19AUG2016	<p>Add the following catalog numbers for HeartSpan® Fixed Curve Braided Transseptal Sheath :</p> <table> <tr> <td>FCB856345</td> <td>FCB8581120</td> </tr> <tr> <td>FCB858145</td> <td>FCB8563135</td> </tr> <tr> <td>FCB8563MLO</td> <td>FCB8581135</td> </tr> <tr> <td>FCB8581MLO</td> <td>FCB8563150</td> </tr> <tr> <td>FCB856390</td> <td>FCB8581150</td> </tr> <tr> <td>FCB858190</td> <td>FCB8563ML1</td> </tr> <tr> <td>FCB8563120</td> <td>FCB8581ML1</td> </tr> </table>	FCB856345	FCB8581120	FCB858145	FCB8563135	FCB8563MLO	FCB8581135	FCB8581MLO	FCB8563150	FCB856390	FCB8581150	FCB858190	FCB8563ML1	FCB8563120	FCB8581ML1
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X	14SEP2016	<p>Add the following catalog numbers for private labeled HeartSpan® Fixed Curve Braided Transseptal Sheath :</p> <p>FCL-196-01 FCL-196-02 FCL-196-07</p>														
Y	09MAR2018	<p>Remove the following PNs :</p> <p>FND-015-xx XD-1779-xx FND-022-xx FCL-173-xx FCL-176-xx</p>														
Z	28JUN2018	<p>Update ISO Cert from « ISO 13485 :2003 – certificate number 3809162 » to « EN ISO 13485:2016 – certificate number 3820098 ». Include "ISO 13485: 2016 MDSAP – certificate number 3830098"</p>														



AA	31JAN2019	Add the following PNs : FCB8563MR0 FCB8581MR0																																																
AB	11MAR2019	Add the following PNs : FCB8563ML2 FCB8581ML2																																																
AC	08JUL2019	Add the following PNs : FCB8560MP18 FCB8560MP28 FCB8561MUL																																																
AD	20-DEC-2019	Add the following PNs : FND-019-00/A FND-019-01/A FND-019-02/A FND-019-03/A FND-019-04/A FND-019-05/A FND-019-06/A																																																
AE	17-MAR-2020	Change Legal Manufacturer <table border="1"> <thead> <tr> <th>From</th> <th>To</th> </tr> </thead> <tbody> <tr> <td>Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern, PA 19355 USA</td> <td>Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 USA</td> </tr> </tbody> </table>	From	To	Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern, PA 19355 USA	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 USA																																												
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AG	21-May-2020	Add the following PNs : FND-019-01/B FND-019-02/B FND-019-03/B FND-019-04/B FND-019-05/B FND-019-06/B																																																
AH	26-AUG-2020	Add the following PNs : <table> <tbody> <tr> <td>FCL-160-00/A</td> <td>FCL-191-00/A</td> <td>FCL-196-01/A</td> <td>FCB856345/A</td> </tr> <tr> <td>FCL-160-01/A</td> <td>FCL-191-01/A</td> <td>FCL-196-02/A</td> <td>FCB858145/A</td> </tr> <tr> <td>FCL-160-02/A</td> <td>FCL-191-02/A</td> <td>FCL-196-07/A</td> <td>FCB8563MR0/A</td> </tr> <tr> <td>FCL-160-03/A</td> <td>FCL-191-03/A</td> <td></td> <td>FCB8581MR0/A</td> </tr> <tr> <td>FCL-160-04/A</td> <td>FCL-191-04/A</td> <td></td> <td>FCB8563ML0/A</td> </tr> <tr> <td>FCL-160-05/A</td> <td>FCL-191-05/A</td> <td></td> <td>FCB8581ML0/A</td> </tr> <tr> <td>FCL-160-06/A</td> <td>FCL-191-06/A</td> <td></td> <td>FCB856390/A</td> </tr> <tr> <td>FCL-160-07/A</td> <td>FCL-191-07/A</td> <td></td> <td>FCB858190/A</td> </tr> <tr> <td>FCL-160-08/A</td> <td>FCL-191-08/A</td> <td></td> <td>FCB8563120/A</td> </tr> <tr> <td>FCL-160-09/A</td> <td>FCL-191-09/A</td> <td></td> <td>FCB8581120/A</td> </tr> <tr> <td>FCL-160-10/A</td> <td>FCL-191-10/A</td> <td></td> <td>FCB8563135/A</td> </tr> <tr> <td></td> <td></td> <td></td> <td>FCB8581135/A</td> </tr> </tbody> </table>	FCL-160-00/A	FCL-191-00/A	FCL-196-01/A	FCB856345/A	FCL-160-01/A	FCL-191-01/A	FCL-196-02/A	FCB858145/A	FCL-160-02/A	FCL-191-02/A	FCL-196-07/A	FCB8563MR0/A	FCL-160-03/A	FCL-191-03/A		FCB8581MR0/A	FCL-160-04/A	FCL-191-04/A		FCB8563ML0/A	FCL-160-05/A	FCL-191-05/A		FCB8581ML0/A	FCL-160-06/A	FCL-191-06/A		FCB856390/A	FCL-160-07/A	FCL-191-07/A		FCB858190/A	FCL-160-08/A	FCL-191-08/A		FCB8563120/A	FCL-160-09/A	FCL-191-09/A		FCB8581120/A	FCL-160-10/A	FCL-191-10/A		FCB8563135/A				FCB8581135/A
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 FCB8560MP28/A
 FCB8561MUL/A

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AI	03-DEC-2020	Update Catalog number for FND-025-xx/A series Add FCL-201-00/A, FCL-201-01/A, FCL-201-02/A, FCL-201-03/A	
AJ	19-JAN-2021	Update Catalog Number for FND-020-XX/B series. Add FND-020-01/B, FND-020-02/B, FND-020-03/B, FND-020-05/B, and FND-020-06/B.	
AK	24-MAY-2021	Add the following part numbers for private labeled HeartSpan® Transseptal Needle & Stylet: FND-026-01/A FND-026-02/A FND-026-03/A FND-026-05/A FND-026-06/A Replace signature from Timothy Stoudt to Glenn Norton	
AL	01-JUNE-2021	Administrative corrections: 1) Added "SHEATH" to Catalog No. (Model No.) for part number series FCL-191-xx/A 2) Removed part number FCL-191-10/A. It has been obsoleted	