MDD CE Mark Extension Memo (EU) 2023/607

Product Name(s)	TEC/TDF	MDD Certificate(s)	EU MDR Class	Extended MDD Date
HeartSpan Fixed Curve Braided Sheath	TDF0182	3809162CE01	III	31-DEC-2027
HeartSpan Transseptal Needle				

Prepared By: (print)	Desiree Bond		
Prepared by: (sign)	Desiree Bond	**Date:**	May 3, 2023
Approved by: (print)	Tom Haueter		
Approved by: (sign)	Tom Haueter (May 3, 2023 14:56 MDT)	**Date:**	May 3, 2023

With respect to the certificates issued under Council Directive 93/42/EEC on medical devices ("MDD"), ("Directive Certificates") and their validity per Article 120.2 of Regulation (EU) 2017/745 on medical devices as amended by Regulation 2023/607 of 20 March 2023 ("MDR") and with respect to the Devices' and its Manufacturer's compliance with the conditions to continued placing on the market or putting into service per Article 120.3 of the MDR:

We, as the Manufacturer confirm

- the above listed product and associated certificates meet the conditions for the legal extension of validity as required in Article 120.2 of the MDR.
- the **Device(s)** listed above are in compliance with the conditions listed in Article 120.3 of the MDR for continued placing on the market and putting into service

Namely, the Directive Certificate covering the listed Devices:

☒ Has been issued after 25 May 2017

☒ Has not been withdrawn by 20 March 2023

☒ Was valid on 26 May 2021 and did not expire before 20 March 2023

☒ The Device(s) continue to comply with the MDD

☒ The Device(s) have not been significantly changed in its design and intended purpose since 26 May 2021.

☒ The Device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health

☒ A quality management system in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024

☒ A formal application to the Notified Body in accordance with Section 4.3, first subparagraph, of Annex VII, MDR for conformity assessment has been made for the Device(s) listed or their substitutes, and a corresponding written agreement in accordance with Section 4.3, second subparagraph, of Annex VII has been signed by us and the Notified Body

☒ Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with the MDR – as far as possible and required - is in place for the Device(s) listed

MDD CE Mark Extension Memo HeartSpan Transseptal Devices

Final Audit Report 2023-05-03

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