



EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

EN

Manufacturer: FIAB SpA

Registered address: Via Costoli 4, 50039 Vicchio (FI), Italia

Single Registration Number: IT - MF - 000005988

Basic UDI-DI: 803300326105000026MM

Product name: Threshold cable for cardiac stimulation

Intended Purpose: Threshold cable used for connection between a threshold analyzer (PSA) and a temporary cardiac lead

Models: See list in Attachment

Technical Documentation File: TDF 105

Risk Class (MDR Annex VIII): IS

Conformity assessment procedure performed: Annex IX - Chapter I and Chapter III

Notified Body: BSI Group The Netherlands B.V.
2797

Certificate(s) issued: EU quality management system certificate:
MDR 747884 R000

**Technical standards and/or
Common Specifications applied:**

EN ISO 10993-1 [2020], EN ISO 13485 [2016/A11:2021], EN ISO 14971 [2019/A11:2021], EN ISO 15223-1 [2021], EN ISO 20417 [2021], EN 556-1 [2024], EN 60601-1 [2006]+A1+A12+A2 [2021], EN ISO 11135 [2014/A1:2019], EN 62366-1 [2015/A1:2020]

With this Declaration of Conformity, issued under the sole responsibility of FIAB SpA as the Manufacturer, we hereby declare:

- that the medical devices specified meet the provision of the Regulation (EU) 2017/745 for medical devices;
- that the procedures of FIAB quality management system according to ISO 13485 have been followed, Certificate of Registration no.MD77846 issued by BSI;
- that the products do not contain medicinal substances, elements of animal origin or their derivatives, human blood derivatives
- are latex free

Signature

Alberto Calabrò
Managing Director

Vicchio, 27/08/2025

Declaration Code EU-105000026-105-3

Cod 99500201MD4C

First issued: 06/12/2022

Last revised: 27/08/2025



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Attachment of EU Declaration of Conformity - List of models

F7830/MED, F7830/TEKASB, F7830DIN, F7830IS-1, F7830S, F7830SL, F7831S, F7832/MED, F7832S, F7833, F7833/4, F7833E, F7833IS-1, F7833L, F7834, F7834/JP, F7834/JP2-250, F7834/JP-250, F7834/JP3-250, F7834/JP4-250, F7834OSY-250, F7837S, F7838

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