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:	803300326105000012MA
Product name:	Reusable bipolar extension cables
Intended Purpose:	Cables for temporary cardiac electrostimulation to be connected to temporary leads with unprotected terminals of Ø <= 2mm
Models:	See list in Attachment
Technical Documentation File:	TDF 105
Risk Class (MDR Annex VIII):	I
Conformity assessment procedure performed:	Annex IV (EU Declaration of Conformity)

Technical standards and/or Common Specifications applied:	EN ISO 13485 [2016/A11:2021], EN ISO 14971 [2019/A11:2021], EN ISO 15223-1 [2021], EN ISO 20417 [2021], EN 60601-1 [2006]+A1+A12+A2 [2021], EN 62366-1 [2015/A1:2020]

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

Digitally signed by Ermicev Alexandr
Date: 2026.01.21 10:21:21 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

Declaration Code	EU-105000012-105-2	First issued:	02/09/2021
Cod 99500038MD4B		Last revised:	27/08/2025

bsi ISO 13485 Quality Management Systems CERTIFIED MD 77846

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

EN

Attachment of EU Declaration of Conformity - List of models

F7816/30, F7816/33, F7816/33/SF, F7816/33JP, F7816/33JP-300, F7816/B30, F7816/B33, F7816/B33/SF, F7816/BBIO, F7816/BIO, F7816/BMED, F7816/BMED015, F7816/BRED, F7816/MED, F7816/MED015, F7816/RED

Declaration Code	EU-105000012-105-2	First issued:	02/09/2021
Cod 99500038MD4B		Last revised:	27/08/2025