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:	803300326808000005TZ
Product name/ Intended Purpose	Disposable electrodes defibrillation,cardioversion,cardiac stimulation,ECG
Models:	See list in Attachment
Technical Documentation File	TDF 808
Risk Class (MDR Annex VIII):	IIB
Conformity assessment procedure performed:	Annex IX – Conformity assessment based on a quality management system (Chapter I)
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 60601-1 [2006/A1:2013] - EN 60601-1-2 [2015] - EN 60601-2-4 [2010/AMD1:2018] - EN ISO 10993-1 [2020] - EN ISO 13485 [2016] - EN ISO 14971 [2019] - EN ISO 15223-1 [2021] - EN ISO 20417 [2021]

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, and are latex free

Signature:

Vicchio, 17/04/2024

Alberto Calabrò
Managing Director

Declaration Code EU-00000596-808

First issued: 11/05/2023

Last revised: 17/04/2024

Cod 99500201MD4A

FIAB SpA – 50039 Vicchio - Firenze - Italia
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Cap. Soc. int. vers. 2.000.000,00 € - C.F.-P.I. e n. Reg. Imp. FI 01835220482 - Trib. FI. n.33541
C.C.I.A.A. FI n. 339066 REA - c/c postale 14476501 - EUROPEAN VAT: IT 01835220482

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Attachment of EU Declaration of Conformity – List of models

F7750U - F7761U - F7786UW-D700 - F7950U - F7950UW - F7961U - F7961UW - F7961UWXL - F7986UW - F7986UW-D700 - F7989UW - F7992U -

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