



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: 803300326808000004TX

Product name: Disposable electrodes defibrillation, cardioversion, cardiac stimulator, ECG

Intended Purpose: External defibrillation, cardioversion, ECG monitoring, transthoracic cardiac electrostimulation

Models: See list in Attachment

Technical Documentation File: TDF 808

Risk Class (MDR Annex VIII): IIB

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 R00

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

EN ISO 10993-1 [2020], EN ISO 13485 [2016], EN ISO 14971 [2019], EN ISO 15223-1 [2021], EN ISO 20417 [2021], EN 60601-1 [2006/A1:2013], EN 60601-1-2 [2015], EN 60601-2-4 [2011/A1:2019]

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, 26/09/2024

Declaration Code EU-808000004-808-1

Cod 99500201MD4B

First issued: 11/05/2023

Last revised: 26/09/2024



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Attachment of EU Declaration of Conformity - List of models

F7750P, F7751P, F7751PW, F7752P, F7752PW, F7753P, F7754P, F7755P, F7756P, F7761P, F7938PW, F7950P, F7950PL, F7950PW, F7950WPL, F7951P, F7951PW, F7952P, F7952PL, F7952PW, F7952WPL, F7953P, F7953PW, F7954P, F7955P, F7955PW, F7956P, F7956PW, F7957PL, F7958P, F7958PL, F7958PW, F7959P, F7959PL, F7959WPL, F7961P, F7961PW, F7962P, F7964PW, F7964W, F7965P, F7965PW/NG, F7966WPL, F7967P, F7967PW, F7968PL, F7969PW, F7970P, F7972P, F7981P, F7983PW, F7986P, F7986PW, F7987PW, F7988PW, U7750P, U7751P, U7752P, U7755P, U7950P, U7951P, U7952P, U7955P, U7961P

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