



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/ 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 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, and are latex free

Signature:

Vicchio, 18/09/2023

Alberto Calabrò
Managing Director

Declaration Code	EU-00000557-808	First issued:	11/05/2023
Cod	99500201MD4A	Last revised:	18/09/2023

Pagina 1 di 2





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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 - F7952PW/MIN - F7952WPL - F7953P - F7953PW - F7954P - F7955P - F7955PW - F7956P - F7956PW - F7957PL - F7958P - F7958PL - F7958PW - F7959P - F7959PL - F7959WPL - F7961P - F7961PW - F7962P - F7964PW - F7965P - F7966WPL - F7967P - F7967PW - F7968PL - F7969PW - F7970P - F7972P - F7981P - F7983PW - F7986P - F7986PW - F7987PW - F7988PW - - F7750P

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Pagina 2 di 2

