



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:	803300326608000001SB
Product name/ Intended Purpose	ECG Electrodes
Models:	See list in Attachment
Technical Documentation File	TDF 608
Risk Class (MDR Annex VIII):	I
Conformity assessment procedure performed:	Annex IV (EU Declaration of Conformity)
Technical standards and/or Common Specifications applied:	ANSI AAMI EC12 [2000 (R:2015)] - EN 1041 [2008/A1:2013] - EN ISO 10993-1 [2018] - EN ISO 13485 [2016] - EN ISO 14971 [2019] - EN ISO 15223-1[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, and are latex free

Signature: _____ Vicchio, 08/04/2022

Alberto Calabrò
Managing Director



Declaration Code EU-00000316-608 First issued: 31/05/2021

Cod 99500038MD4B Last revised: 08/04/2022





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Attachment of EU Declaration of Conformity – List of models

F2017 - F2017/4FL - F2017H - F2017P - F2060P - F2069RM - F2080 - F2080/60 - F2080P - F3001ECG - F3001ECG/1000 - F3001NECG - F3002ECG - F3002ECG/30 - F9046 - F9046RM - F9047 - F9047/4F - F9047/4FL - F9047/8 - F9047/8MRI - F9047RM - F9048 - F9049/100 - F9060 - F9060P - F9067 - F9069NRM - F9069PRM - F9069RM - F9070 - F9070P - F9070RM - F9079/100 - F9079/XL - F9079P/100 - F9089/100 - F9089/30 - F9089GL - F9089P/100

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