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:	8033003260080000001MZ
Product name/ Intended Purpose	Reusable electrodes for ECG
Models:	See list in Attachment
Technical Documentation File	TDF 008
Risk Class (MDR Annex VIII):	I
Conformity assessment procedure performed:	Annex IV (EU Declaration of Conformity)
Technical standards and/or Common Specifications applied:	EN 1041 [2008/A1:2013] - EN 60601-1 [2006/A1:2013] - EN ISO 13485 [2016] - EN ISO 14971 [2018] - EN ISO 15223-1 [2016]

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, 14/06/2021

Alberto Calabrò

Managing Director

Declaration Code	EU-00000025-008	First issued:	26/05/2021
		Last revised:	14/06/2021

Cod 99500038MD4B

FIAB SpA – 50039 Vicchio - Firenze - Italia
Sede legale: Via P. Costoli, 4 - Logistica: Via Meglini, 2-4
Unità operative: Via Passerini, 2-3-4-6 – Via della Resistenza, 18
Tel. +39 0558497999 - Fax +39 0558497979 - www.fiab.it
Cap. Soc. int. vers. 2.000.000,00 € - C.F.P.I. e n. Reg. Imp. FI 01835220482 - Trib. FI. n.3354 I
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

F9002NI - F9002SSC - F9003NI - F9003SSC - F9007 - F9007P - F9007PL - F9008NI - F9008PLUS - F9008SSC - F9009NI - F9009PLUS - F9009SSC - F9009ULTRA - F9010PSSC - F9010SSC - F9010SSC-6 - F9015SSC - F9016NI - F9016PLUS - F9016SSC - F9016ULTRA - F9023NI - F9023PLUS - F9023SSC - F9024CSSC - F9024NI - F9024ONI - F9024OSSC - F9024PLUS - F9024SSC - F9024SSCGI - F9024SSCNE - F9024SSCRG - F9024SSCRO - F9024SSCVE - F9024ULTRA

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