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:	803300326109000001P9
Product name/ Intended Purpose	Adapters for ECG-electrostimulation connector cables
Models:	See list in Attachment
Technical Documentation File	TDF 109
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 [2019] - 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, 01/07/2021

Alberto Calabrò

Managing Director

Declaration Code EU-00000055-109

First issued: 27/05/2021

Last revised: 01/07/2021

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

F9017/4PW - F9017W - F9019/2N - F9019/2R - F9019F4N15 - F9019F4N20 - F9019F4R15 - F9019F4R20 - F9019FN - F9019FR - F9019N - F9019NDIN100 - F9019R - F9019RDIN100 - PG922/24N - PG922/24R - PG922/2CN - PG922/2CR - PG922/2MN - PG922/2MR - PG922/2TN - PG922/2TR - PG922/42N - PG922/42R - PG922/4KIT - PG922/4KIT5 - PG922/4KIT5W - PG922/4MMR - PG922/4MN - PG922/4MR - PG922/4TB - PG922/4TG - PG922/4TN - PG922/4TR - PG922/4TV - PG922/CN2 - PG922/CR2 - PG922/F42TPN - PG922/MCN - PG922/MCR

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