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:	803300326130000002LB
Product name/ Intended Purpose	Gel ECG spray
Models:	See list in Attachment
Technical Documentation File	TDF 130
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 ISO 10993-1 [2018] - 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, 03/06/2021

Alberto Calabrò

Managing Director

Declaration Code	EU-00000002-130	First issued:	03/06/2021
		Last revised:	03/06/2021

Cod 99500038MD4B

FIAB SpA – 50039 Vicchio - Firenze - Italia
Sede legale: Via P. Costoli, 4 - Logistica: Via Meglini, 2-4
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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

G004

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