



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:	803300326108000006P2
Product name/ Intended Purpose	Reusable electrodes electrostimulation "easystim"
Models:	See list in Attachment
Technical Documentation File	TDF 108
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 [2019] - EN ISO 15223-1 [2016]

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, 12/10/2021

Alberto Calabrò
Managing Director

Declaration Code EU-00000129-108

First issued: 12/10/2021

Cod 99500038MD4B

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Attachment of EU Declaration of Conformity – List of models

PG701 - PG702 - PG703 - PG704 - PG704/2C - PG705 - PG706 - PG706/2C - PG707 - PG721 - PG722 - PG723 - PG724 - PG725

Declaration Code	EU-00000129-108	First issued:	12/10/2021
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