



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:	803300326108000001NQ
Product name/ Intended Purpose	Conductive silicone electrodes
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, 01/07/2021

Alberto Calabrò
Managing Director

Declaration Code EU-00000061-108

First issued: 29/06/2021

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Attachment of EU Declaration of Conformity – List of models

PG912/2 - PG912/22 - PG912/4 - PG912/41N - PG912/41R - PG912/44 - PG912/45R - PG912/51N - PG912/51R - PG916/2 - PG916/22 - PG916/4 - PG916/41N - PG916/41R - PG916/44 - PG916/51N - PG916/51R - PG917/4 - PG917/41N - PG917/41R - PG917/44 - PG917/51N - PG917/51R - PG925/2 - PG925/4 - PG950/2 - PG950/22 - PG950/4 - PG950/44 - PG960/75 - PG960/95 - PG970/2 - PG970/22 - PG970/4 - PG970/41N - PG970/41R - PG970/44 - PG970/51N - PG970/51R - PG971/2 - PG971/2W - PG971/40W - PG971/45W - PG980/2 - PG980/22 - PG980/4 - PG980/41N - PG980/41R - PG980/44 - PG980/51N - PG980/51R - PG980/F4P

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