



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: 803300326108000005NY

Product name/ Intended Purpose: Spontex electrodes holding bags

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 ISO 10993-1[2020] - EN ISO 13485 [2016] - EN
ISO 14971 [2019] - EN ISO 15223-1[2021] - EN ISO
20417 [2021]

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, 06/10/2023

Alberto Calabrò
Managing Director

Declaration Code EU-00000563-108

First issued: 11/10/2021

Last revised: 28/09/2023

Cod 99500038MD4B

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Attachment of EU Declaration of Conformity – List of models

PG9009Y - PG9025Y - PG9050Y - PG9060Y - PG9070Y - PG9080Y - PG9100Y - PG912S - PG912S-6 - PG912S/1 - PG912S/QUATTRO - PG912S2 - PG916S - PG916S-6 - PG916S/1 - PG917S - PG917S/1 - PG917S/DUE - PG9200Y - PG970S - PG970S-6 - PG970S/1 - PG970S/DUE - PG980S - PG980S-6 - PG980S/1 - PG980S/DUE - PG980S/QUATTRO - PG980S2 - PG9X100100S - PG9X105150S2 - PG9X110140S2 - PG9X110150S - PG9X115175S2 - PG9X120125S2/SY - PG9X130230S - PG9X135195S2 - PG9X140195S2 - PG9X195140S2 - PG9X45110SL - PG9X6075S/QUATTRO - PG9X6090S2 - PG9X80110S2 - PG9X80130S - PG9X8050S - PG9X8070S - PG9X90105S - PG9X90105S2 - PG9X90110S2

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