



EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

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|---|---|
| Manufacturer: | FIAB SpA |
| Registered address: | Via Costoli 4, 50039 Vicchio (FI), Italia |
| Single Registration Number: | IT-MF-000005988 |
| Basic UDI-DI: | 80330032620800001PF |
| Product name/ Intended Purpose | Fully gelled electrodes for neurostimulation |
| Models: | See list in Attachment |
| Technical Documentation File | TDF 208 |
| 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, 14/06/2023

Alberto Calabrò
Managing Director

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| Declaration Code | EU-00000524-208 | First issued: | 09/06/2021 |
| Cod | 99500038MD4B | Last revised: | 14/06/2023 |

Pagina 1 di 2





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Attachment of EU Declaration of Conformity – List of models

PG100 - PG200 - PG200W - PG200WN - PG470 - PG470/MIC - PG470L - PG470LN - PG470N - PG470N/500 - PG470W - PG470WN - PG471 - PG471/40 - PG471/40N - PG471/40W - PG471/40WN - PG471/50 - PG471/50W - PG471/50W-16 - PG471/50WN - PG471/63W - PG471/63WN - PG471L - PG471N - PG471W - PG471WN - PG472 - PG472/2C - PG472/90 - PG472/90W - PG472N - PG472W - PG472W2 - PG472WN - PG473 - PG473/2 - PG473/2N - PG473L - PG473LN - PG473N - PG473W - PG473W2 - PG473W2N - PG473W2N/DUE - PG473WN - PG474 - PG474L - PG474N - PG474W - PG474WN - PG475 - PG475L - PG475LN - PG475W - PG476 - PG476L - PG476N - PG476W - PG477 - PG477N - PG477W - PG479/32 - PG479/32N - PG479/32W - PG479/32WN - PG479/50 - PG479/50N - PG479/50W - PG479/50WN - PG479/75 - PG479/75W - PG479/75WN - PG479OVW - PG480/95W2 - PG490 - PG490N - PG691WN - PG771/50 - PG771/50W - PG772/902 - PG772/90W - PG774W - PG871/40W - PG871/50 - PG871/50W - PG873 - PG873N - PG873W - PG873W2 - PG874W - PG879/32N - PG879/32W - PG879/50W - PG879/75 - PG880/95W2 - PG880/95W2N - PG890W

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Pagina 2 di 2

