EU Declaration of conformity

Spes Medica S.p.A.

Via Buccari 21 – 16153 Genova (GE) Italia

Certificated: EN ISO 13485:2016 Medical devices – Quality management system – system requirements for regulatory purposes.

Single Registration Number (SRN): IT-MF-000008858

Declares under its responsibility that the devices:

Electroencephalography (EEG) needle electrodes

BASIC UDI-DI: 8054655000010XR
Risk class: IIA, Rule 7
Conformity Assessment Route: Annex IX, Chapters I and III
Intended use: The Needle Electrodes are intended for use for the recording of biopotential signals with recording, monitoring and stimulation equipment for neurophysiology, examples include: Electromyography (EMG), Electroencephalography (EEG), intraoperative monitoring (IOM) and evoked potentials (EP).

MN2013D10S	Subdermal needle electrode 0,20x13mm, 100cm cable, DIN42802

Fulfil the general safety and performance requirements of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.
As stated by the certificate No 105/MDR, issued by notified body IMQ (0051) , Via Quintiliano 43-20138 Milano - Italy

Giuseppe Mafrici

CEO

Genova, 16/07/2024