



CERTIFICATE ATESTATION OF CONFORMITY

Manufacturer: QUANTUM MEDICAL SRL

Address: Str. Miron Costin nr. 61, Satu Mare, judet Satu Mare, Romania, email info@quantum-medical.ro – VAT no. RO 43216173

Product(s): Universal electrophysiological system of ED.X type biofeedback, having as its use the therapy of pain caused by various traumas, through (MENS [microcurrent transcutaneous electro-nerval stimulation) and the treatment of neuromuscular dystonia and muscle contractions, muscle tension and/or muscle spasm through muscle re-education (EMG; EEG-based visual-haptic biofeedback)

Commercial brand: UNIVERSAL ELECTROPHYSIOLOGICAL BIOFEEDBACK SYSTEM

Product type(s) / model(s): ED.X

Applicable EC directives: 2014/30/EU – relating to Electromagnetic compatibility (“EMC”)
2014/35/EC relating to the making available on the market of electrical equipment designed for use within certain voltage limits (“LVD”)

Harmonised standards: EN 60601-1-2:2015 + A1:201
EN 60601-1:2006/A2:2021
EN 60601-2-10:2015/A1:2016
EN 60601-2-26:2015

Test report(s) and date(s): Test Reports no. 167 / 14.03.2023 si Nr. 177 / 20.03.2023 by laboratory OICPE – LICPE, adresa Splaiul Unirii 313, lot 2, parter din constructia P+4, C1-U63, 030198, sector 3, Bucuresti - Romania, email oicpe@oicpe.ro, RENAR accreditation certificate no. LI 911.

This certificate is valid just for the analysed product design in the voluntary product certification scheme.
The certificate shall loses its validity in case of any changes in the product.

Ultimate responsibility regarding the affixing of CE mark according to relevant regulations and legal legislation, belongs to the manufacturer.

Certificate no.: SWC-AC-0107-24
Issue date: February 12th, 2024
Expiry date: February 12th, 2029



Constantin Catalin
Certification Manager



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