ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЗЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

EC CERTIFICATE
PRODUCTION QUALITY ASSURANCE

issued in accordance with Annex 5 of Government Order No. 54/2015 Coll.
(Annex V of Directive 93/42/EEC)

No.: MED 200065

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **2EL, spol. s r.o.**
Na Staré Cidlině 663, 504 01 Nový Bydžov, Czech Republic

in manufacturing sites **2EL, spol. s r.o.**
Machkova 587, 500 11 Hradec Králové, Czech Republic

for manufacturing and final inspection of medical device(s)

Magnetotherapeutic device for physical therapy, stimulation and medical rehabilitation, class IIa
Type: LT-99 + adapter FW8001M / 12 (ULTICARE LT-99)
LT-100 + adapter FW8001M / 12 (Bio Torus, Dia Torus)
Optional external applicators: A1C, A4C, ASE and B1C

meets the provisions of Annex 5 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex V of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. MED000047-02/01 of: 02.04.2020,

MED000047-03/01 of: 13.08.2020.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 5 clause 4 of Government Order No. 54/2015 Coll. (Annex V clause 4 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate was issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

This certificate can be used for class IIb and III medical devices together with EC Type-Examination Certificate only, issued in accordance with Annex 3 of Government Order 54/2015 Coll. (Annex III of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 04.09.2020 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

04.09.2020

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
Stamp

* C E R / M E D 2 0 0 0 6 5 *

Certificate history

Date	Status	Reason
04.09.2020	Issuance	

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja