

EU declaration of conformity

Manufacturer: MEDEXIM, spol. s r.o., Hlboká 58,
921 01 Piešťany, Slovak Republic

Product name: Balneological hydromassage device BTL-3000
Type: ALFA 10, ALFA 20,
DELTA 10, DELTA 20,
OMEGA 20,
KAPPA 10, KAPPA 20,
BETA 10, BETA 20,
THETA 10, THETA 20,
ZETA 10, ZETA 20

Classification of medical device: IIa (Annex IX, rule 9)

Conformity assessment procedures: Annex VI of the Directive 93/42/EEC as amended

Standards: MEDDEV 2.4/1 rev 9, MEDDEV 2.7/1 rev.4,
MEDDEV 2.12/1 rev. 8., MEDDEV 2.12/2 rev.2
EN 60601-1:2006/A1:2013/AC:2014/A2:2021,
EN 60601-1-2:2015/A1:2021, EN 60601-1-6:2010/A1:2015/A2:2021,
EN 62366-1:2015/AC:2015/A1:2020, EN ISO 10993-5:2009, EN
62304:2006/A1:2015, EN ISO 14971:2019, EN ISO 13485:2016, EN
ISO 15223-1:2021

Name and number notified body (NB): 3EC International a.s., Notified Body No. 2265

Number EC certificate: 2019-MDD/QS-024, validity extended until 31.12.2028 see
Notified Body Confirmation Letter No. 2265 dated 26.5.2023

Number certificates Quality management systems: ISO 9001:2015: Q-0163/24, valid until 13.03.2028
EN ISO 13485:2016: M-0103/24, valid until 13.03.2028

We hereby declare that the above medical device fulfilled all the requirements of Council Directive 93/42/EEC concerning medical devices as amended.

All the basic documents, including technical documents are kept by the manufacturer.

This medical device is marked with CE.

In Piešťany, March 14th, 2025



Ing. Marek Šintál - Director

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