EU declaration of conformity

Manufacturer:	MEDEXIM, spol. s r.o., Hlboká 58, 921 01 Piešťany, Slovak Republic
Product name:	Balneological hydromassage device
Type:	AQUADELICIA I, AQUADELICIA II, AQUADELICIA III, AQUADELICIA IV, AQUADELICIA V, AQUADELICIA VI, AQUADELICIA VII, AQUADELICIA VIII, AQUADELICIA IX, AQUADELICIA GS, AQUADELICIA GL, AQUADELICIA MINI, AQUADELICIA MINI I, AQUADELICIA MINI II, AQUADELICIA MINI III, AQUADELICIA MINI III L, AQUADELICIA MINI III LB, AQUAMANUS, AQUAPEDIS, AQUAPEDIS I, AQUAPEDIS II, AQUABELA, AQUABELA M, ARES, ARES RELAX, ARES DOUBLE
Classification of medical device:	IIa (Annex VIII, 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:	2018-MDD/QS-016/A, 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-0163/22, valid until 13.03.2025 EN ISO 13485:2016: M-0103/22, valid until 13.03.2025

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, June 23th, 2023

Medexim spol. s r.o. Hlboká 58 921 01 PIEŠŤANY

Ing. Marek Šintál - Director