3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2018-MDD/QS-016/A

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIa,

Balneological hydromassage device:
AQUADELICIA I, AQUADELICIA II, AQUADELICIA III, AQUADELICIA IV, AQUADELICIA V, AQUADELICIA VI, AQUADELICIA VII, AQUADELICIAVIII, AQUADELICIA IX, AQUADELICIA MINI, AQUADELICIA MINI I, AQUADELICIA MINI II, AQUADELICIA MINI III, AQUADELICIA MINI III L, AQUADELICIA MINI III LB, AQUADELICIA GS, AQUADELICIA GL, AQUAMANUS, AQUAPEDIS, AQUAPEDIS I, AQUAPEDIS II, AQUABELA, AQUABELA M, ARES, ARES RELAX, ARES DOUBLE

manufactured by company

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

is manufactured under conditions fulfilling the quality system requirements of Annex VI. of the Directive 93/42/EEC as amended.

The Notified Body No. 2265 has performed an audit of the above device quality system. The product quality assurance has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex VI. Sections 3.3. and 4. of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310308 No.SK-0193-20 and the Final protocol No. 310308B/2020.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until June 30th 2023 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body 3EC International 2265 OSOBA

Dr. Katarína Tomin Sidošová
Responsible to act on behalf of NB 2265

Digitally signed by Cobzari-Țurcan Rodica
Date: 2025.10.13 18:04:45 EEST
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In Bratislava, on March 24th, 2020
Version A) supersedes EC Certificate No. 2018-MDD/QS-016 issued on July 1st, 2018