



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

## EC CERTIFICATE

No. 2019-MDD/QS-024

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC,  
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 BTL-3000:**  
**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**

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 by 2007/47/EC.

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 2007/47/EC. The detailed description of the system, requirements and measures  
applied by the manufacturer are presented in the Audit Report No. SK-0193-19 and the Final protocol No.  
310360/2019.

*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  
March 17<sup>th</sup>, 2024 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.



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

In Bratislava, on March 18<sup>th</sup>, 2019