3EC®
international

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

Attn. Dipl. Ing. Marek Šintál, statutory representative

Our reference	*Contact person*	BRATISLAVA
LUL/2023/P005	Ľubor Lysák / +421 2 5831 8343	26.05.2023

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number (if available): SK-MF-000015788

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

3EC International a.s. ⑥
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
VAT No.: SK2022390073

Katarína Tomin Srdošová, PhD.
Director of NB2265

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CO2 Gas Injector **INCO2, INCO2 FLUO, INCO2 ELEGANCE**	Class IIa	N/A	2018-MDD/QS-017/A; NB2265
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, AQUAMANUS, AQUAPEDIS,**	Class IIa	N/A	2018-MDD/QS-016/A; NB2265 2019-MDD/QS-024; NB2265

AQUAPEDIS I, AQUAPEDIS II, AQUABELA, AQUABELA M, ARES, ARES RELAX, ARES DOUBLE 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			

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/23	LUL/2023/P005	Initial issue