1stQ GmbH
Konrad-Zuse-Ring 23
68163 Mannheim
Germany

Attn. Thomas Diehm, Technical managing director, QMB, PRRC

Our reference	***Contact person***	BRATISLAVA
MIT/2026/P133	Michal Tomin / +421 915 366 774	05th June, 2026

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 and implementing Regulation (EU) 2023/1194 amending implementing Regulation (EU) 2022/2346 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:

1stQ GmbH
Konrad-Zuse-Ring 23
68163 Mannheim
Germany

SRN Number (if available): DE-MF-000013177

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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)
- 31 December 2028 for Annex XVI products which do not require a clinical investigation. * (applicable for - see table 1)
- 31 December 2029 for Annex XVI products which require a clinical investigation. ** (applicable for - see table 1)

On behalf of the Notified Body,

3EC International a. s.
Hraničná 18, 821 05 Bratislava
Slovenská republika
IČO: 36 789 003
IČ DPH: SK2022390073

Katarína Tomin Srdošová, PhD.
Director of NB 2265

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
Posterior chamber intraocular lens, pseudophakic, hydrophilic monofocal: G Monofocal : 613AD, Z Monofocal : B1AW00, S1AW00 Z Monofocal Toric: B1TP0T, S1TP0T, S1TP00 Q Monofocal: B2AP00, S2AP00 Q Monofocal: B2AW00, S2AW00 B Monofocal: 677AD B Monofocal Toric: 677TA B Monofocal Toric: 677CTA B Monofocal: 677P multifocal: B Full Range: 677M B Full Range Toric: 677MT Z Full Range: B1EP0N, S1EP0N Q Full Range: B7EP0N, S7EP0N Posterior chamber intraocular lens, pseudophakic, hydrophilic, blue light filter monofocal: Z Monofocal: B1AWY0, S1AWY0	Class IIb implantable non-WET device	Monofocal organic ophthalmic lenses substituted to Posterior chamber intraocular lens, pseudophakic, hydrophilic And Posterior chamber intraocular lens, pseudophakic, hydrophilic, blue light filter Model K Monofocal : 611HPS was substituted to Model G Monofocal : 613AD	Certificate: 6420GB410210524A NB 0482

Z Monofocal Toric: B1TWYT, S1TWYT, S1TWY0 Z Monofocal Toric: B1TPYT, S1TPYT, S1TPY0 Q Monofocal: B2AWY0, S2AWY0 Q Monofocal : B2APY0, S2APY0 B Monofocal: 677ADY, 677PY B Monofocal Toric: 677TAY, 677CTAY multifocal Z Full Range: B1EPYN, S1EPYN, B1EWYN, S1EWYN Z Full Range Toric: B1HPYN, S1HPYN, B1HWYN, S1HWYN B Full Range: 677CMY, 677PMY, 677MY B Full Range Toric: 677CMTY, 677MTY Q Full Range: B2EWYN, S2EWYN, B2EPYN, S2EPYN			
Posterior chamber intraocular lens, pseudophakic, hydrophobic monofocal Z Monofocal: B1AD00, S1AD00 B Monofocal: 877FAB Posterior chamber intraocular lens, pseudophakic, hydrophobic, blue light filter monofocal Z Monofocal: B1ADY0,S1ADY0 B Monofocal: 877FABY B EDOF: 877EBY	Class IIb implantable non-WET device	Monofocal organic ophthalmic lenses substituted to Posterior chamber intraocular lens, pseudophakic, hydrophobic And Posterior chamber intraocular lens, pseudophakic, hydrophobic, blue light filter	Certificate: 6420GB410210524A NB 0482
Posterior chamber intraocular lens, pseudophakic, hydrophobic, blue light filter, preloaded in a single use injector monofocal B Monofocal Toric: 877PTY Z Monofocal: B1ABY0, S1ABY0 Z Monofocal Toric: B1TBY0, S1TBY0 Z Mono+: 860PAY Z Mono+ Toric: 860PTY B Monofocal: 877PAY	Class IIb implantable non-WET device	Monofocal organic ophthalmic lenses substituted to Posterior chamber intraocular lens, pseudophakic, hydrophobic, blue light filter, preloaded in a single use injector And Posterior chamber intraocular lens, pseudophakic,	Certificate: 6420GB410210524A NB 0482

Z EDOF: B1XBY0, S1XBY0 Z EDOF Toric: B1ZBY0, S1ZBY0 Z EDOF+: 860PEY Z EDOF+ Toric: 860PETY B EDOF: 877PEY B EDOF Toric: 877PETY Posterior chamber intraocular lens, pseudophakic, hydrophobic, preloaded in a single use injector monofocal B Monofocal: 877PA B Monofocal Toric: 877PT Z Monofocal : B1AB00, S1AB00 Z Monofocal Toric: B1TB00,S1TB00		hydrophobic, preloaded in a single use injector	
Posterior chamber intraocular lens, pseudophakic, hydrophilic, for implantation into the ciliary sulcus: monofocal AddOn Refractive: A4SW00 AddOn Monofocal Toric: A4TW0T AddOn Monofocal Toric: A4TW00 AddOn Monofocal Toric: A4FW00 AddOn Monofocal Toric: A4FW0T multifocal: AddOn Full Range: A4DW0M AddOn Full Range: A4EW0M AddOn SML: A4MW00 AddOn EDOF 1,75: A4DW0H AddOn EDOF 2,25: A4DW0K AddOn EDOF 1,75: A4EW0H AddOn EDOF 2,25: A4EW0K AddOn Full Range Toric: A4HW0M	Class IIb implantable non-WET device	Monofocal organic ophthalmic lenses substituted to Posterior chamber intraocular lens, pseudophakic, hydrophilic, for implantation into the ciliary sulcus : monofocal Multifocal organic ophthalmic lenses substituted to Posterior chamber intraocular lens, pseudophakic, hydrophilic, for implantation into the ciliary sulcus: multifocal	Certificate: 6420GB410210524A NB 0482

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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	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

	verified at the pre-application stage)		
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2026/06/05	MIT/2026/P133	Initial issue