SELF -DECLARATION REGARDING THE IMPLEMENTATION OF REGULATION (EU) 2023/607 - EXTENSION OF THE MDR TRANSITIONAL PERIOD

We, MEDICONTUR Medical Engineering Ltd. hereby declare under our exclusive responsibility that

- the products listed below continue to comply with the requirements of the European Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC of the European Parliament and the Council of 5 Sept 2007, as well as with the other applicable laws, regulations and directives.
- there are no significant changes in the design and intended purpose and
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- we implemented a quality management system (QMS) in accordance with MDR Article 10(9).
- no later than 26 May 2024, in accordance with the first subparagraph of Article 4.3 of MDR Annex VII for conformity assessment with regard to the devices in question we made an official application to a notified body
- no later than 26 September 2024, a written agreement has been signed between the relevant notified body and MEDICONTUR Medical Engineering Ltd. in accordance with the second subparagraph of Article 4.3 of Annex VII to MDR

Proposal number of MDR certification with SGS Belgium NV (NB 1639): HU/BUD/2164
Date of the contract: 08.03.2023
Application date: 24.01.2023.
Notified body under MDR: SGS Belgium NV (Notified body No. 1639)
Seat: SGS House Noorderlaan 87 2030 Antwerp Belgium

Contract number of MDR certification with 3EC International a.s (NB 2265):
Contract on Medical Device conformity assessment no. SK-0714-MDR/23 signed by Chairman of the Board of Directors – Katarina Tomin Srdosova, PhD. on date 12.9.2023

Scope of application: Please refer to the product list below.

Considering the above, the extension conditions of REGULATION (EU) 2023/607 are met and the devices may be placed on the market or put into service until the following dates:
- **31 December 2027**, for all class III devices, and for **class IIb implantable devices** except 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

Design and manufacturing are in compliance with the applicable harmonized standards published in the Official Journal of the European Union. All supporting documentation – including the list of applicable standards – is retained at the premises of the manufacturer.

Manufacturer: MEDICONTUR Medical Engineering Ltd.
2072 Zsámbék, Herceghalmi út 1., Hungary

Contact information: bbodosi@medicontur.hu

Product identification under the scope of MDR application:

MDR application at NB 2265:

Classification: Class IIb according to Annex IX of 93/42/EEC rule 8

Product name	Model	Brand name	Basic UDI-DI
Posterior chamber intraocular lens, pseudophakic, hydrophilic	640PM	Q-Flex Trifocal Preloaded	599302640PMYV
	640P	Q-Flex Preloaded	599302640PD5
	677AD	Bi-Flex	599302677ADYN
	677P	Bi-Flex Preloaded	599302677PE9
	677TA	Bi-Flex T	599302677TA2C
	677M	Trifocal Bi-Flex Liberty	599302677MF3
	677MT	Trifocal Toric Bi-Flex Liberty	599302677MT2V
	677CTA	Bi-Flex T Preloaded	599302677CTARP
	640AD	Q-Flex	599302640ADWW
	690TA	Z-Flex T	599302690TAZL
	690CM	Trifocal Z-Flex Preloaded	599302690CMYR
	690CTA	Z-Flex T Preloaded	599302690CTAQU
	690AD	Z-Flex	599302690ADXZ
Posterior chamber intraocular lens, pseudophakic, hydrophilic, blue light filter	677ADY	Bi-Flex	599302677ADYRD
	640ADY	Q-Flex	599302640ADYNT
	677PY*	Bi-Flex Preloaded	599302677PY3G
	677TAY	Bi-Flex T	599302677TAYU3
	677MY	Trifocal Bi-Flex Liberty	599302677MY37
	677MTY	Trifocal Toric Bi-Flex Liberty	599302677MTYUR
	677PMY	Trifocal Bi-Flex Liberty Preloaded	599302677PMYUK
	677CTAY	Bi-Flex T preloaded	599302677CTAYND
	677CMY	Trifocal Bi-Flex Liberty preloaded	599302677CMYSJ
	677CMTY	Trifocal Toric Bi-Flex Liberty preloaded	599302677CMTYP3
	640CMY	Trifocal Q-Flex Preloaded	599302640CMYPY
	640MY	Q-Flex Trifocal	599302640MYZC
	640PY	Q-Flex Preloaded	599302640PYZM
	690ADY	Z-Flex	599302690ADYQJ
	690TAY	Z-Flex T	599302690TAYT8
	690MY	Z-Flex Trifocal	599302690MY2J
	690MTY	Z-Flex Trifocal Toric	599302690MTYTW
	690CMY	Trifocal Z-Flex preloaded	599302690CMYRP
	690CMTY	Trifocal Toric Z-Flex preloaded	599302690CMTYMG
	690CTAY	Z-Flex T preloaded	599302690CTAYLS

Product name	Model	Brand name	Basic UDI-DI
Posterior chamber intraocular lens, pseudophakic, hydrophobic	860FAB	Z-Flex HB	599302860FABPD
	877FAB	Bi-Flex HB	599302877FABR9
Posterior chamber intraocular lens, pseudophakic, hydrophobic, blue light filter	860FABY	Z-Flex HB	599302860FABYJE
	877EBY	Bi-Flex ELON HB	599302877EBYSM
	877FABY	Bi-Flex HB	599302877FABYM8

Product name	Model	Brand name	Basic UDI-DI
Posterior chamber intraocular lens, pseudophakic, hydrophobic, preloaded in a single use injector	860PA	Z-Flex POB-MA	599302860PAZ9
	860PT	Z-Flex Toric POB-MA	599302860PT2J
	877PA	Bi-Flex POB-MA	599302877PA2N
	877PT	Bi-Flex Toric POB-MA	599302877PT3U
Posterior chamber intraocular lens, pseudophakic, hydrophobic, blue light filter, preloaded in a single use injector	860PAY	Z-Flex POB-MA	599302860PAYSD
	860PTY	Z-Flex Toric POB-MA	599302860PTYU6
	860PEY	Z-Flex EDOF POB-MA	599302860PEYSR
	860PETY	Z-Flex EDOF Toric POB-MA	599302860PETYNW
	877PAY	Bi-Flex POB-MA	599302877PAYU9
	877PTY	Bi-Flex Toric POB-MA	599302877PTYW2
	877PEY	Bi-Flex ELON POB-MA	599302877PEYUM
	877PETY	Bi-Flex ELON Toric POB-MA	599302877PETYRQ

MDR application at NB1639:

Classification: Class IIb according to Annex IX of 93/42/EEC rule 8

Product name	Model	Brand name	Basic UDI-DI
Sterile Capsular Tension Ring Preloaded in a Single Use Injection Kit	11ACB	JetRing	599302Jetring11ACB2K
	12ACB	JetRing	599302Jetring12ACB2S

Product name	Model	Basic UDI-DI
Sterile Viscoelastic solutions for ophthalmic use:	BioVis 1.6%	599302BioVis1.6%Q6
	BioVis 1.8%	599302BioVis1.8%QC
	BioVis 3.0%	599302BioVis3.0%Q2
	VISCO-MC	599302VISCO-MCNB

Classification: Class IIa according to Annex IX of 93/42/EEC rule 6

Product name	Model	Brand name	Basic UDI-DI
Sterile single use foldable lens injector	PIL-MA	Medjet PIL-MA injection system	599302MedjetPIL-MANP

Product name	Model	Brand name	Basic UDI-DI
Disposable Injection Kit	Medjet MC 1.6	Medjet	599302MedjetMC1.67E
	Medjet MB 1.8	Medjet	599302MedjetMB1.87B
	Medjet MA 2.2	Medjet	599302MedjetMA2.26V
	Medjet MX 2.4 HB	Medjet	599302MedjetMX2.4HBVK

Conformity assessment: according to Annex II excluding section 4 of 93/42/EEC

Notified Body under 93/42/EEC: SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium

Notified Body Number: 1639

CE Certificate: HU19/8471

Zsámbék, 21 Nov 2023

MEDICENTUR
Medical Engineering Ltd.
2072 Zsámbék, Herceghalmi út 1.
Hungary

Krisztina Lipták
Senior Quality Engineer