Manufacturer's declaration

in respect to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 (EU-MDR)

We

HumanOptics Holding AG
Spardorfer Str. 150
91054 Erlangen
Germany

hereby declare on our own responsibility with respect to the Regulation (EU) 2017/745 amended by Regulation (EU) 2023/607 that

our medical devices of risk class IIb marked with CE mark are placed on the market in accordance with the provisions stated in the European regulations and that we are fulfilling the following conditions (see Article 120 / EU-MDR) for the continued placing on the market and putting into service after expiry of our approval according to Council Directive 93/42/EEC on Medical Devices (EU-MDD):

- The devices continue to comply with the Directive 93/42/EEC even after our approval has expired.
- There are no significant changes in design and intended purpose.
- The devices do not present an unacceptable risk to the health or safety of patients, users or other persons or to protection of public health.
- We have lodged an application for conformity assessment before 26 May 2024 to get the certificates according to EU-MDR.
- We have implemented an QM system documentation according to EU-MDR no later than 26 May 2024.
- We have already started the required conformity assessments for product compliance according to EU-MDR which are still pending approval, also after the expiring date of our current valid EC approval issued by TÜV Rheinland according to 93/43/EC (26 May 2024).

We hereby confirm that the extension of the transitional period to 31 December 2027 applies to all our products in the scope of our current approval, as the regulatory required conditions are fulfilled.

Therefore, we confirm the validity of our approval issued for our Legacy Devices under MDD until 31 December 2027.

Erlangen, May 13th 2024

Alexander Berka

CEO

HUMANOPTICS

Products in the scope of our current approval, that are covered by this self-declaration:

Product	Packaging variant	GMDN code	Risk class (EU-MDR)
Intraocular lenses		35658 Lens, intraocular, posterior chamber made of acrylic	IIb (implant)
Aspira-aA	Compact Line (CL)		
	Safeloader (SL)		
Aspira-aAY	Compact Line (CL)		
	Safeloader (SL)		
Aspira-aXA	Compact Line (CL)		
	Safeloader (SL)		
Aspira-aXAY	Compact Line (CL)		
	Safeloader (SL)		
Diff-aA	Safeloader (SL)		
Diff-aAY	Safeloader (SL)		
Triva-aA	Compact Line (CL)		
	Safeloader (SL)		
Triva-aAY	Compact Line (CL)		
	Safeloader (SL)		
TrivaT-aA	Compact Line (CL)		
	Safeloader (SL)		
TrivaT-aAY	Compact Line (CL)		
	Safeloader (SL)		
Triva-aXA	Compact Line (CL)		
	Safeloader (SL)		
Triva-aXAY	Compact Line (CL)		
	Safeloader (SL)		
TrivaT-aXA	Compact Line (CL)		
	Safeloader (SL)		
TrivaT-aXAY	Compact Line (CL)		
	Safeloader (SL)		
Torica-aA	Compact Line (CL)		
Torica-aAY	Compact Line (CL)		
Torica-aXA	Compact Line (CL)		
	Safeloader (SL)		
Torica-aXAY	Compact Line (CL)		
	Safeloader (SL)		
MC X11 ASP	Compact Line (CL)		

AB

Products in the scope of our current approval, that are covered by this self-declaration:

Product	**GMDN code**	**Risk class (EU-MDR)**
Artificial Iris	60894 Implantable Iris prosthesis / ophthalmic implants, Iris	IIb (implant)
Artificial Iris with Fiber		
Artificial Iris Fiber Free		

AB