

EC-Declaration of Conformity

We

**HumanOptics Holding AG
Spardorfer Str. 150
91054 Erlangen
Germany**

declare on our own responsibility that

**the medical devices of the class IIb, named in the annex,
marked with the CE-mark,
meet all the requirements of the Directive 93/42/EEC concerning medical devices and
fulfil the quality requirements of the Directive 93/42/EEC concerning medical devices
annex II excluding section 4.**

**Notified Body 0197: TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany**

This declaration of conformity is valid until 26.05.2024 according to the current certificate Directive 93/42/EEC annex II with the registration number HD 2339954-1.

Erlangen, 08 December 2021



**Stefan Kremer
CEO**

Annex to the Declaration of Conformity

The EC-Declaration of Conformity is valid for the following class IIb medical devices:

Nr.	Produkt	UMDNS Nr.	GMDN code	Klasse
1	LENS, INTRAOCULAR, POSTERIOR CHAMBER MADE OF ACRYLIC (1PIECE): AS Aspira-aA Aspira-aA SL Aspira-aAY Aspira-aAY SL Aspira-aXA Aspira-aXA SL Aspira-aXAY Aspira-aXAY SL Diff-aA Diff-aA MF Diff-aA SL Diff-aA MF SL Diff-aAY Diff-aAY MF Diff-aAY SL Diff-aAY MF SL Diff-aA BF Diff-aA BF SL Diff-aAY BF Diff-aAY BF SL Triva-aA Triva-aA SL Triva-aAY Triva-aAY SL TrivaT-aA TrivaT-aA SL TrivaT-aAY TrivaT-aAY SL Triva-aXA Triva-aXA SL Triva-aXAY Triva-aXAY SL TrivaT-aXA TrivaT-aXA SL TrivaT-aXAY TrivaT-aXAY SL Torica-aA Torica-aA SL Torica-aAY Torica-aAY SL ToricaDiff-aA ToricaDiff-aA SL	16-071	35658	IIb

Nr.	Produkt	UMDNS Nr.	GMDN code	Klasse
	ToricaDiff-aAY			
	ToricaDiff-aAY SL			
	Torica-aXA			
	Torica-aXA SL			
	Torica-aXAY			
	Torica-aXAY SL			
	MC X11 ASP			
	LENS, INTRAOCULAR, POSTERIOR CHAMBER MADE OF ACRYLIC (3PIECE):			
	Aspira3P-aVA			
	Aspira3P-aVAY			

Nr.	Produkt	UMDNS Nr.	GMDN code	Klasse
2.	IMPLANTABLE IRIS PROSTHESIS / OPHTHALMIC IM- PLANTS, IRIS (ArtificialIris):	34509	60894	IIb
	Artificial Iris with Fiber			
	Artificial Iris Fiber Free			