

EU Technical Documentation Assessment Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapter II

The Notified Body of TÜV NORD CERT GmbH certifies that the assessment of the technical documentation for the manufacturer

HumanOptics Holding AG
Spardorfer Straße 150
91054 Erlangen
Germany

of the named device in accordance with Regulation (EU) 2017/745 Annex IX, chapter II (4) was performed during which the device was found to conform with the relevant provisions of Regulation (EU) 2017/745 for medical devices.

Any change to the approved device requires approval from the Notified Body. This Certificate by itself does not permit to affix the CE-marking on the product, a valid certificate according to Annex IX, chapter I and III including the products mentioned on this certificate is required in addition.

Single Registration Number of the Manufacturer (SRN):	DE-MF-000017892
Authorised Representative:	see Section 1
Limitations and Conditions:	see Section 2
List of Products, Risk Classification and Details:	see Section 3
Certificate History:	see Section 4

Certificate number:	44 912 221836	Valid from:	2026-02-16
Certification decision report No.:	3541 0293	Valid until:	2030-06-12
		First issued:	2025-06-13
		Issue date:	2026-02-16
		Edition:	2

B. Hoy

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

EU Technical Documentation Assessment Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapter II

Certificate number: 44 912 221836

Section 1, Authorised Representative

Company name:	N/A
Street, No.:	--
Postal Code, City:	--
Country:	--

Section 2, Limitations and Conditions

The validity of this Certificate depends on:	N/A
and the following conditions:	--
and / or is limited to the following:	--



EU Technical Documentation Assessment Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,

Annex IX, Chapter II

Certificate number: 44 912 221836

Section 3, List of Products, Risk Classification and Details

CLASS IIB, implantable

Generic device group (EMDN):	P030102090202 IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES IOLs, APHAKIC, MONOFOCAL, ASPHERIC, HYDROPHILIC ACRYLIC 3536 4177
TD assessment report no.:	
Basic UDI-DI:	Devices or groups of devices:
04049154_PC_M2_H2_O2_BU	IOLs, aphakic / Family Aspira-aA/Y
04049154_PC_M2_H3_O2_C7	IOLs, aphakic / Family MC X11 ASP
04049154_PC_M2_H4_O2_CJ	IOLs, aphakic / Family Aspira-aXA/Y
Intended use:	Intended for implantation in the capsular bag to replace the natural lens
Model:	Aspira-aA Aspira-aA+ Aspira-aAY Aspira-aAY+ Aspira-aXA Aspira-aXAY MC X11 ASP

Generic device group (EMDN):	P030102090302 IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES IOLs, APHAKIC, MONOFOCAL, TORIC, HYDROPHILIC ACRYLIC 3536 4178
TD assessment report no.:	
Basic UDI-DI:	Devices or groups of devices:
04049154_PC_M2_H2_O3_BX	IOLs, aphakic / Family Torica-aA/Y
04049154_PC_M2_H4_O3_CM	IOLs, aphakic / Family Torica-aXA/Y
Intended use:	Intended for implantation in the capsular bag to replace the natural lens
Model:	Torica-aA Torica-aAY Torica-aXA Torica-aXAY

EU Technical Documentation Assessment Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,

Annex IX, Chapter II

Certificate number: 44 912 221836

Generic device group (EMDN):	P030102100202 IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES IOLs, APHAKIC, MULTIFOCAL, ASPHERIC, HYDROPHILIC ACRYLIC
TD assessment report no.:	3536 4240
Basic UDI-DI:	Devices or groups of devices:
04049154_PC_M2_H2_O4_C2	IOLs, aphakic / Family Diff-aA/Y
	IOLs, aphakic / Family Triva-aA/Y
04049154_PC_M2_H4_O4_CQ	IOLs, aphakic / Family Triva-aXA/Y
Model:	TrivaT-aA TrivaT-aAY TrivaT-aXA TrivaT-aXAY

Generic device group (EMDN):	P030102100302 IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES IOLs, APHAKIC, MULTIFOCAL, TORIC, HYDROPHILIC ACRYLIC
TD assessment report no.:	3536 4241
Basic UDI-DI:	Devices or groups of devices:
04049154_PC_M2_H2_O5_C5	IOLs, aphakic / Family TrivaT-aA/Y
04049154_PC_M2_H4_O5_CT	IOLs, aphakic / Family TrivaT-aXA/Y
Intended use:	Intended for implantation in the capsular bag to replace the natural lens
Model:	TrivaT-aA TrivaT-aAY TrivaT-aXA TrivaT-aXAY

Generic device group (EMDN):	P0399 IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES OCULAR PROSTHESES - OTHER
TD assessment report no.:	3536 4242
Basic UDI-DI:	Devices or groups of devices:
04049154_AI_M1_H1_O1_X7	Artificial Iris
Intended use:	Intended for use as an iris prosthesis for the treatment of iris defects in eyes which are pseudophakic, aphakic or requiring cataract extraction; intended for implantation in the posterior chamber (ciliary sulcus)
Model:	Artificial Iris with Fiber Artificial Iris Fiber Free

EU Technical Documentation Assessment Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapter II

Certificate number: 44 912 221836

Section 4, Certificate History

Edition	Date	Action leading to revision	Certification decision report No.
1	2025-06-13	Initial certification	3536 4175
2	2026-02-16	Devices added	3541 0293

