EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

HumanOptics Holding AG
Spardorfer Straße 150
91054 Erlangen
Germany

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. For devices of class IIb and IIa the surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III devices and class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

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:	44 911 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

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

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Annex IX, Chapters I and III
Certificate number: 44 911 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:	--

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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
TD assessment report no.:	3536 4177
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

Generic device group (EMDN):	P030102090302 IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES IOLs, APHAKIC, MONOFOCAL, TORIC, HYDROPHILIC ACRYLIC
TD assessment report no.:	3536 4178
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

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Certificate number: 44 911 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
Intended use:	Intended for implantation in the capsular bag to replace the natural lens

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

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)

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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

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