Number: 2254207CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

OPHTEC B.V.

Schweitzerlaan 15
9728 NR Groningen
The Netherlands
SRN ID.: NL-MF-000000048

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 49290CN

Additional certificate: 2254207TD01, 2254207TD02

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **8 November 2022** Date: **12 February 2024** Expiry date**: 1 November 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

IOLs, APHAKIC, MONOFOCAL, ASPHERIC, HYDROPHILIC ACRYLIC (P030102090202, class IIb implantable)	
Device Name: PRECIZON Monofocal	*Intended Purpose:* *Intraocular lens intended to be placed into the capsular bag of the eye after extracapsular cataract extraction, functioning as a refractive medium to replace the human crystalline lens and to correct aphakia*

IOLs, APHAKIC, MONOFOCAL, TORIC, HYDROPHILIC ACRYLIC (P030102090302, class IIb implantable)	
Device Name: PRECIZON Toric	*Intended Purpose:* *Intraocular lens intended to be placed into the capsular bag of the eye after extracapsular cataract extraction, functioning as a refractive medium to replace the human crystalline lens and to correct aphakia and corneal astigmatism*

IOLs, APHAKIC, MULTIFOCAL, ASPHERIC, HYDROPHILIC ACRYLIC (P030102100202, class IIb implantable)	
Device Name: PRECIZON Presbyopic NVA	*Intended Purpose:* *Intraocular lens intended to be placed into the capsular bag of the eye after extracapsular cataract extraction, functioning as a refractive medium to replace the human crystalline lens and to correct aphakia and presbyopia*

IOLs, APHAKIC, MULTIFOCAL, TORIC, HYDROPHILIC ACRYLIC (P030102100302, class IIb implantable)	
Device Name: PRECIZON Presbyopic Toric	*Intended Purpose:* *Intraocular lens intended to be placed into the capsular bag of the eye after extracapsular cataract extraction, functioning as a refractive medium to replace the human crystalline lens and to correct aphakia, presbyopia and corneal astigmatism*

IOLs, APHAKIC, MONOFOCAL, ASPHERIC, HYDROPHILIC ACRYLIC (P030102090202, class IIb implantable)	
Device Name: PRECIZON GO	*Intended Purpose:* *Intraocular lens Intended to be placed into the capsular bag of the eye after extracapsular cataract extraction, functioning as a refractive medium to replace the human crystalline lens and to correct aphakia*

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IOLs, APHAKIC, MONOFOCAL, ASPHERIC, HYDROPHILIC ACRYLIC (P030102090202, class IIb implantable)	
Device Name: PC 545Y QuadrimaX Aspheric	*Intended Purpose:* *Intraocular lens Intended to be placed into the capsular bag of the eye after extracapsular cataract extraction, functioning as a refractive medium to replace the human crystalline lens and to correct aphakia*

IOLs, PHAKIC, MONOFOCAL, SPHERICAL, SILICONE (P030101030103, class IIb implantable)	
Device Name: ARTIFLEX Myopia	*Intended Purpose:* *Intraocular lens intended to be fixated to the iris tissue of the eye, functioning as a refractive medium to correct myopia.*

IOLs, PHAKIC, MONOFOCAL, TORIC, SILICONE (P030101030303, class IIb implantable)	
Device Name: ARTIFLEX Toric	*Intended Purpose:* *Intraocular lens intended to be fixated to the iris tissue of the eye, functioning as a refractive medium to correct myopic astigmatism.*

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Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	8 November 2022	49290CN26	First issue
1	23 August 2023	49290CN29	Revised issue
2	31 August 2023	49290CN30	Revised issue
3	12 February 2024	49290CN31	Revised issue

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