DECLARATION OF CONFORMITY HYDROPHILIC ACRYLIC INTRAOCULAR LENSES

We hereby declare that the distributed CE marked products, specified in the product lists mentioned below, conform to the products covered by the 'EU Quality Management System Certificate' with number 2254207CE01, issued for the first time on November 8, 2022 and delivered by DEKRA Certification B.V, Arnhem, The Netherlands, Notified Body identification number 0344, in accordance with Annex IX of the of the Regulation (EU) 2017/745 of 5 April 2017 on medical devices. This declaration is issued under the sole responsibility of OPHTEC B.V.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb, implantables devices and long-term surgically invasive devices (rule 8 of the Regulation (EU) 2017/745 of 5 April 2017 on medical devices, annex VIII) devices meet the provisions of the Regulation which apply to them.

This declaration is based on the application of the management system approved for design, manufacture and final inspection of the products concerned in accordance with Annex IX of the Regulation. The conformity of the full quality assurance system set out in Annex IX, is described in the said EC Certificate, issued and delivered by DEKRA Certification B.V.

This declaration is supported by the Quality System certification based on the standard EN ISO 13485:2016, Management System Certificate with number 49289, issued for the first time on May 1, 2001 and delivered by DEKRA Certification B.V.

This Declaration of Conformity is valid for all products concerned bearing the CE marking and manufactured at the following location:

OPHTEC B.V.
Schweitzerlaan 15
9728 NR Groningen
The Netherlands
SRN number: NL-MF-000000048

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This Declaration of Conformity covers the product family 'Hydrophilic Acrylic intraocular lenses' which consists of the following products identified by:

Model	Name	CE marked dd.	Basic UDI-DI	Intended purpose/use
560	PRECIZON Monofocal	02 Jul 2012	8717819Precizon560/6B	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
565	PRECIZON Toric	25 Sep 2013	8717819Precizon565/6S	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
570	PRECIZON Presbyopic NVA	19 Apr 2018	8717819Precizon570/6G	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
575	PRECIZON Presbyopic Toric	18 Mar 2020	8717819Precizon575/6X	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

Issued on
Date November 17, 2022
Place Groningen

Signature

A. Takens

A. Takens
Person Responsible for Regulatory Compliance (PRRC)