OPHTEC
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DECLARATION OF CONFORMITY MEDICAL DEVICES - INTRAOCULAR DEVICES & ACCESSORIES

We hereby declare that the distributed CE marked products, specified in the product list mentioned below, conform to the products covered by the " EC Certificate" with number 49290CE01, issued for the first time on February 1, 1995 and delivered by DEKRA Certification B.V, Arnhem, The Netherlands, Notified Body identification number 0344, in accordance with Annex II of the European Council Directive 93/42/EEC of June 14, 1993, concerning medical devices as amended by 2007/47/EC of September 5, 2007.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb, implantable devices and long-term surgically invasive devices (rule 8 of the EC Directive 93/42EEC, annex IX) devicesmeet the provisions of the EC Directive 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 II of the EC-Directive. The conformity of the full quality assurance system set out in Annex II, 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 covers the following product families as specified in the following product lists:

- "PMMA intraocular devices"

PMMA intraocular lenses	A001000074
PMMA tension rings	A001000077
Preloaded PMMA tension rings	A001000267

- "Silicone intraocular devices"

Silicone intraocular lenses	A001000078

- "Hydrophilic Acrylic intraocular devices"

Hydrophilic Acrylic intraocular lenses	A001000083

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

Reissued on
Date 2 July 2018
Place Groningen

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Signature

A. Takens

Mr. A. Takens
Manager Quality Assurance & Regulatory Affairs

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DECLARATION
PRODUCT LIST CE - PMMA INTRAOCULAR LENSES

This product list belongs to the Declaration of Conformity identified by A001000079 for "PMMA Intraocular Lenses" and specifies the CE marked products concerned that OPHTEC B.V. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by 2007/47/EC of September 5, 2007. The following list identifies the products by:

REF	Name	Subfamily	CE marked dd.
130**1W	ARTISAN Toric Sxx*Cxx* 0°	Artisan Toric	24 Apr 2001
140**1W	ARTISAN Toric Sxx*Cxx*90°	Artisan Toric	24 Apr 2001
203001W	ARTISAN Hyperopia 5/8.5	Artisan Phakic	20 Jun 1997
204001W	ARTISAN Myopia 6/8.5	Artisan Phakic	27 Feb 1998
204US1W	ARTISAN Myopia 6/8.5	Artisan Phakic	8 Jan 2009
205001R	ARTISAN aphakia 5/8.5	Artisan Aphakia	19 Jun 1997
205001Y	ARTISAN Aphakia 5/8.5	Artisan Aphakia	19 Jun 1997
206001W	ARTISAN Myopia 5/8.5	Artisan Phakic	6 Jul 1997
206US1W	ARTISAN Myopia 5/8.5	Artisan Phakic	8 Jan 2009

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