SELF-DECLARATION EXTENDED TRANSITION PERIOD MDD CE CERTIFICATE 49290CE01 & 49290CE02

To whom it may concern:

We,

OPHTEC BV
Schweitzerlaan 15
9728 NR Groningen
The Netherlands
SRN number: NL-MF-000000048

declare that the following distributed CE marked products will benefit from the extended transition period according Regulation (EU) 2023/607 which amends Regulation (EU) 2017/745;

Device Name	Model	MDR Classification	CE certificate no.
PRECIZON Monofocal PRECIZON Toric PRECIZON Presbyopic NVA PRECIZON Presbyopic Toric PC545Y QuadrimaX Aspheric PC525* ErgomaX	560 565 570 575 5450*TY 52501T*	Class IIb (implantable)	49290CE01
ARTISAN Toric ARTISAN Hyperopia 5/8.5 ARTISAN Myopia 6/8.5 ARTISAN Myopia 5/8.5 ARTISAN Aphakia 5/8.5	1*0**1W 203001W 204001W 206001W 205001*		
ARTIFLEX Myopia ARTIFLEX Toric	40114SW 4*0**SW		
Capsular Tension Ring 12/10 Capsular Tension Ring 13/11	275001G 276001G		
RingJect 12/10 RingJect 13/10	375BT1G 376BT1G		
Enclavation Needle Insertion Spatula	OD125* OD110	Class IIa	49290CE02

*indicates variables due to different configurations

We meet all the requirements for the continued validity of MDD (Directive 93/42/EEC) certification past the expiration date which is July 2023 and the product may be placed on the market or put into service into the EU under the MDD certificates 49290CE01 (class IIb) and 49290CE02 (class IIa);

-until 31st December 2027 for class IIb (implantable) products and
-until 31st December 2028 for class IIa products.

The MDD CE certificates are delivered by DEKRA Certification B.V., Arnhem, The Netherlands with Notified Body identification number 0344.

We hereby confirm, according Regulation (EU) 2023/607, that the conditions for the extension are fulfilled:
-the devices continue to comply with Directive 93/42/EEC;
-there are no significant changes in the design and intended purpose;
-the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
-OPHTEC BV has put in place a quality management system in accordance with Article 10(9);
-no later than 26 May 2024, OPHTEC BV has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of the above devices, and, no later than 26 September 2024, the notified body and OPHTEC BV have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

Date May 10, 2023
Place Groningen, The Netherlands

Signature A. Takens

A.Takens
Person Responsible for Regulatory Compliance (PRRC)