

# Declaration of Conformity



## *Class III Product – Collamer Implantable Contact Lenses*

### **CONFORMITY ASSESSMENT**

Class III, Rule 8 and Rule 17

Annex II of MDD 93/42/EEC Council Directive

STAAR Surgical AG declares that the above mentioned products meet the provisions of the council directive 93/42/EEC for medical devices which apply to them, including the essential requirements stated in Annex I. This declaration is based on the application of the quality system certification based on the harmonized standard EN ISO 13485:2016, issued on 27 August 2018.

All supporting documentation is retained at the premises of the legal manufacturer.

### **NOTIFIED BODY**

DEKRA Certification BV – 0344

### **CERTIFICATION**

CE Marking of Conformity – 3806368CE01

25 March 2011

EC Design Examination – 3806368DE01

21 April 2011

### **LEGAL MANUFACTURER**

STAAR Surgical AG

Hauptstrasse 104

CH-2560

Nidau

Switzerland

Phone: +41 32 332 8888

Fax: +41 32 332 8899

Philippe Subrin – Vice President, Swiss Operations

### **AUTHORIZATION**

A handwritten signature in blue ink, appearing to read "Evelyn De La Vega".

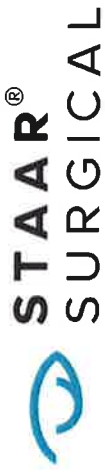
Evelyn De La Vega

Director of Regulatory Affairs

A handwritten date in blue ink: "2018/09/20".

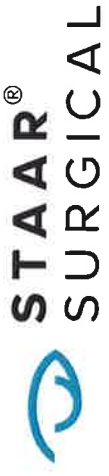
Date

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## Class III Product –Collamer Implantable Contact Lenses

PRODUCTION SITE	MODEL	START DATE	STATUS
STAAR Surgical Company 1911 Walker Avenue Monrovia, CA 91016 Phone: 626-303-7902 Fax: 626-239-1864 Philip Tsung — Senior Director of Quality System	<b>Implantable Collamer Lens for Myopia in BSS</b> VICMO 12.1 VICMO 12.6 VICMO 13.2 VICMO 13.7	21 April 2011 21 April 2011 21 April 2011 21 April 2011	Active Active Active Active
STAAR Surgical AG Hauptstrasse 104 CH-2560 Nidau Switzerland Phone: +41 32 332 8888 Fax: +41 32 332 8899 Philippe Subrin – Vice President, Swiss Operations	<b>Implantable Collamer Lens for Myopia with Astigmatism in BSS</b> VTICMO 12.1 VTICMO 12.6 VTICMO 13.2 VTICMO 13.7	21 April 2011 21 April 2011 21 April 2011 21 April 2011	Active Active Active Active



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STAAR Surgical Company 1911 Walker Avenue Monrovia, CA 91016 Phone: 626-303-7902 Fax: 626-239-1864 Philip Tsung — Senior Director of Quality System	<b>Implantable Collamer Lens for Hyperopia in BSS</b> VICH 11.6 VICH 12.1 VICH 12.6 VICH 13.2	18 May 2010 18 May 2010 18 May 2010 18 May 2010	Active Active Active Active
STAAR Surgical AG Hauptstrasse 104 CH-2560 Nidau Switzerland Phone: +41 32 332 8888 Fax: +41 32 332 8899 Philippe Subrin – Vice President, Swiss Operations	<b>Implantable Collamer Lens for Hyperopia with Astigmatism In BSS</b> VTICH 11.6 VTICH 12.1 VTICH 12.6 VTICH 13.2	18 May 2010 18 May 2010 18 May 2010 18 May 2010	Active Active Active Active

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**PRODUCTION SITE**

STAAR Surgical Company  
 1911 Walker Avenue  
 Monrovia, CA 91016  
 Phone: 626-303-7902  
 Fax: 626-239-1864  
 Philip Tsung — Senior Director of Quality  
 System

**MODEL**

**Implantable Collamer Lens for Hyperopia in BSS**

VICH6 11.6  
 VICH6 12.1  
 VICH6 12.6  
 VICH6 13.2

**START DATE**

08 May 2017  
 08 May 2017  
 08 May 2017  
 08 May 2017

**STATUS**

Active  
 Active  
 Active  
 Active

**Implantable Collamer Lens for Myopia in BSS**

VICM5 12.1  
 VICM5 12.6  
 VICM5 13. 2  
 VICM5 13.7

16 December 2015  
 16 December 2015  
 16 December 2015  
 16 December 2015

Active  
 Active  
 Active  
 Active

VICM6 12.1  
 VICM6 12.6  
 VICM6 13. 2  
 VICM6 13.7

08 May 2017  
 08 May 2017  
 08 May 2017  
 08 May 2017

Active  
 Active  
 Active  
 Active

**Implantable Collamer Lens for Myopia with Astigmatism in BSS**

VTICM5 12.1  
 VTICM5 12.6  
 VTICM5 13.2  
 VTICM5 13.7

16 December 2015  
 16 December 2015  
 16 December 2015  
 16 December 2015

Active  
 Active  
 Active  
 Active





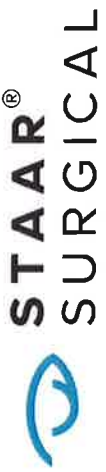
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## Class III Product –Collamer Implantable Contact Lenses

### INACTIVE MODELS

PRODUCTION SITE	MODEL	STATUS
STAAR Surgical Company 1911 Walker Avenue Monrovia, CA 91016 Phone: 626-303-7902 Fax: 626-239-1864 Philip Tsung – Senior Director of Quality System	<b>Implantable Contact Lens for Myopia</b> ICM 115 V4 ICM 120 V4 ICM 125 V4 ICM 130 V4	Inactive Inactive Inactive Inactive
STAAR Surgical AG Hauptstrasse 104 CH-2560 Nidau Switzerland Phone: +41 32 332 8888 Fax: +41 32 332 8899 Philippe Subrin – Vice President, Swiss Operations	<b>Implantable Contact Lens for Myopia and Astigmatism</b> TICM 115 V4 TICM 120 V4 TICM 125 V4 TICM 130 V4	Inactive Inactive Inactive Inactive
	<b>Implantable Contact Lens for Hyperopia</b> ICH 110 V3 ICH 115 V3 ICH 120 V3 ICH 125 V3	Inactive Inactive Inactive Inactive

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### INACTIVE MODELS

PRODUCTION SITE	MODEL	STATUS
STAAR Surgical Company 1911 Walker Avenue Monrovia, CA 91016 Phone: 626-303-7902 Fax: 626-239-1864 Philip Tsung – Senior Director of Quality System	<b>Implantable Collamer Lens for Myopia in BSS</b>	
	VICM 12.1	Inactive
	VICM 12.6	Inactive
	VICM 13.2	Inactive
	VICM 13.7	Inactive
STAAR Surgical AG Hauptstrasse 104 CH-2560 Nidau Switzerland Phone: +41 32 332 8888 Fax: +41 32 332 8899 Philippe Subrin – Vice President, Swiss Operations	<b>Implantable Collamer Lens for Myopia with Astigmatism in BSS</b>	
	VTICM 12.1	Inactive
	VTICM 12.6	Inactive
	VTICM 13.2	Inactive
	VTICM 13.7	Inactive

## *Class III Product –Collamer Implantable Contact Lenses*

### Revision History

#### Revision A

Class III Declaration of Conformity pCIOL – Rev A: 2011/06/09

New document; Declarations of Conformity reformatted and reorganized by class.

#### Revision B

Class III Declaration of Conformity pCIOL – Rev B: 2011/10/20

Declaration of Conformity was revised in response to changes in department heads. Stephanie Shaw replaces Jack Coggan as the authorized signer and David Menneret replaces Philippe Subrin as STAAR Surgical AG contact.

#### Revision C

Class III Declaration of Conformity pCIOL – Rev C: 2012/04/02

Revision history added to Declaration of Conformity.

#### Revision D

Class III Declaration of Conformity pCIOL – Rev D: 2012/12/03

Production site updated to include the Monrovia, California facility, following the partial manufacturing transfer.

#### Revision E

Class III Declaration of Conformity pCIOL – Rev E: 2013/03/12

Production site updated to indicate that ICH and Toric models are not currently manufactured at the Monrovia, California site. These models are still manufactured at the Nidau facility.

#### Revision F

Class III Declaration of Conformity pCIOL – Rev F: 2013/04/17

Included classification rule from MDD.

#### Revision G

Class III Declaration of Conformity pCIOL – Rev G: 2013/09/23

Document has been updated to reflect that addition of the Monrovia facility as a production site for Toric ICL.

#### Revision H

Class III Declaration of Conformity pCIOL – Rev H: 2014/02/18

Document has been update to correct the “start date” for the VICMO and VTICMO models. Format reorganized for clarification.



## *Class III Product –Collamer Implantable Contact Lenses*

### **Revision I**

Class III Declaration of Conformity pCIOL- Rev I: 2014/09/26

Document has been updated to reflect the addition of new preloaded models VICM5P, VTICM5P, VICMOP and VTICMOP

### **Revision J**

Class III Declaration of Conformity pCIOL-Rev J: 2015/07/27

Document has been updated to reflect the organizational change of the STAAR Monrovia Quality Assurance from Don Ellis to Lisa Marston.

### **Revision K**

Class III Declaration of Conformity pCIOL – Rev K: 2015/11/11

Document has been updated to reflect the organizational change of the STAAR Surgical AG Quality Assurance from David Menneret to Natalie Chaise and STAAR Monrovia Quality Assurance from Lisa Marston to Julie Papp.

### **Revision L**

Class III Declaration of Conformity pCIOL – Rev L: 2016/03/01

Document has been updated to reflect the addition of new models VICM5 and VTICM5. Document is also corrected to include Monrovia facility as production site for the ICH, VICH and VTICH models. The Monrovia facility was inadvertently not included as a production site for the ICH, VICH and VTICH models in previous revisions. Other changes include minor formatting changes and correction of typographical errors.

### **Revision M**

Class III Declaration of Conformity pCIOL – Rev M: 2016/11/14

Document has been updated to reflect the organizational change of the STAAR Surgical Company Quality System Representative from Julie Papp to Philip Tsung. Other changes are administrative edits, including formatting adjustment and updating company logo and Monrovia fax number.

### **Revision N**

Class III Declaration of Conformity pCIOL – Rev N: 2017/03/14

Document has been updated to remove ICM, ICH and TICM models from the active device list as these models are discontinued by the manufacturer.

## *Class III Product –Collamer Implantable Contact Lenses*

### **Revision O**

Class III Declaration of Conformity pCIOL – Rev O: 2017/09/21

Document has been updated to reflect the organizational change of the STAAR Surgical AG Quality System Representative from Nathalie Chaise to Michelle Andres, Director of Regulatory Affairs from Stephanie Shaw to Evelyn De La Vega, addition of new models, VICM6 and VICH6.

### **Revision P**

Class III Declaration of Conformity pCIOL – Rev P: 2018/02/20

Recent approvals: Extension of age range in Indications, extension of anterior chamber depth in Indications, alternative autoclave.

### **Revision Q**

Class III Declaration of Conformity pCIOL – Rev Q: 2018/09/20

Document has been updated to reflect this declaration is based on the application of the quality system certification based on the harmonized standard EN ISO 13485:2016, change status of VICM and VTICM from Active to Inactive, organization change from Michelle Andres to Philippe Subrin,