

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

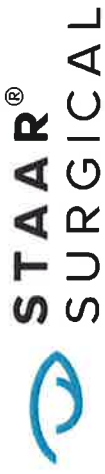
A handwritten signature in blue ink, appearing to read "Evelyn De La Vega".

Evelyn De La Vega
Director of Regulatory Affairs

2018/09/20

Date

Declaration of Conformity



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



Declaration of Conformity

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	Implantable Collamer Lens for Hyperopia in BSS 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	Implantable Collamer Lens for Hyperopia with Astigmatism In BSS 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

Declaration of Conformity



Class III Product –Collamer Implantable Contact Lenses

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

Declaration of Conformity



Class III Product –Collamer Implantable Contact Lenses

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

VISIAN ICL/TICL Preloaded Lenses

VICM5P 12.1
 VICM5P 12.6
 VICM5P 13.2
 VICM5P 13.7

VTICM5P 12.1
 VTICM5P 12.6
 VTICM5P 13.2
 VTICM5P 13.7

VICMOP 12.1
 VICMOP 12.6
 VICMOP 13.2
 VICMOP 13.7

VTICMOP 12.1
 VTICMOP 12.6
 VTICMOP 13.2
 VTICMOP 13.7

START DATE

29 June 2014
 29 June 2014
 29 June 2014
 29 June 2014

29 June 2014
 29 June 2014
 29 June 2014
 29 June 2014

29 June 2014
 29 June 2014
 29 June 2014
 29 June 2014

29 June 2014
 29 June 2014
 29 June 2014
 29 June 2014

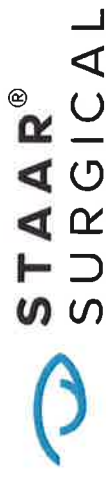
STATUS

Active
 Active
 Active
 Active

Active
 Active
 Active
 Active

Active
 Active
 Active
 Active

Active
 Active
 Active
 Active



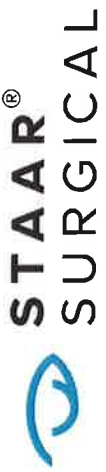
Declaration of Conformity

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	Implantable Contact Lens for Myopia 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	Implantable Contact Lens for Myopia and Astigmatism TICM 115 V4 TICM 120 V4 TICM 125 V4 TICM 130 V4	Inactive Inactive Inactive Inactive
	Implantable Contact Lens for Hyperopia ICH 110 V3 ICH 115 V3 ICH 120 V3 ICH 125 V3	Inactive Inactive Inactive Inactive

Declaration of Conformity



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	Implantable Collamer Lens for Myopia in BSS VICM 12.1 VICM 12.6 VICM 13.2 VICM 13.7	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	Implantable Collamer Lens for Myopia with Astigmatism in BSS VTICM 12.1 VTICM 12.6 VTICM 13.2 VTICM 13.7	Inactive Inactive Inactive 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,