

Declaration of Conformity



Class IIb Products

CONFORMITY ASSESSMENT

Class IIb, Rule 8

Annex II of MDD 93/42/EEC Council Directive

STAAR Surgical Company 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 – 65107CE01

25 March 2011

LEGAL MANUFACTURER

STAAR Surgical Company

1911 Walker Avenue

Monrovia, CA 91016

Phone: 626-303-7902

Fax: 626-239-1864

Philip Tsung — Senior Director of Quality System

AUTHORIZED REPRESENTATIVE

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 that reads "E. De La Vega".

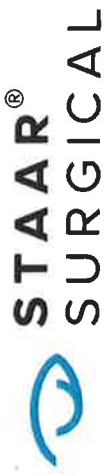
Evelyn De La Vega

Director of Regulatory Affairs

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

Date

Declaration of Conformity



Class IIb Products

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

MODELS

Preloaded Silicone Intraocular Lenses
KS-3AI

START DATE

10 April 2006

STATUS

Active

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Class IIb Products

INACTIVE MODELS

PRODUCTION SITE

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1911 Walker Avenue
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MODELS

Elastic Intraocular Lenses

AA4203
AA4203F
AA4203V
AA4203VF
AA4204VF
AA4204VL
AA4207VF

STATUS

Inactive
Inactive
Inactive
Inactive
Inactive
Inactive
Inactive

Elastic Intraocular Lenses with Toric Optic

AA4203T
AA4203TF
AA4203TL

Inactive
Inactive
Inactive

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INACTIVE MODELS

PRODUCTION SITE

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MODELS

Elastimide Intraocular Lenses

AQ1016
AQ2003
AQ2010
AQ2013
AQ1016V
AQ2003V
AQ2010V
AQ2017V
AQ5010V

STATUS

Inactive
Inactive
Inactive
Inactive
Inactive
Inactive
Inactive
Inactive
Inactive

Preloaded Silicone Intraocular Lenses

KS-1
KS-3

Inactive
Inactive

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Class IIb Products

Revision History

Revision A

Class IIb Declaration of Conformity – Rev A: 2011/06/02

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

Revision B

Class IIb Declaration of Conformity – 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, Donald Ellis Jr. replaces Vijay Pandrangi as head of quality at STAAR Surgical in Monrovia, CA, and David Menneret replaces Philippe Subrin as STAAR Surgical AG contact.

Revision C

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

Revision history added to Declaration of Conformity.

Revision D

Class IIb Declaration of Conformity – Rev D: 2012/08/23

Removed models KS-1 and KS-3 from the Japan production site.

Revision E

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

Removed AA and AQ silicone (non-preloaded) IOLs from the Declaration of Conformity. Products are no longer sold in the EU and there is no inventory at the EU distributor.

Revision F

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

Added Monrovia as a production site, and included classification rule from MDD.

Revision G

Class IIb Declaration of Conformity – Rev G: 2013/09/20

Nidau location removed from list of production sites. Product is manufactured at Monrovia facility.

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Revision H

Class IIb Declaration of Conformity – Rev H: 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 I

Class IIb Declaration of Conformity – Rev I: 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 J

Class IIb Declaration of Conformity – Rev J: 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 adding inactive models for record, formatting adjustment and updating company logo and Monrovia fax number.

Revision K

Class IIb Declaration of Conformity – Rev K: 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.

Revision L

Class IIb Declaration of Conformity – Rev L: 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, Authorized representative from Michelle Andres to Philippe Subrin.