Declaration of Conformity

STAAR® SURGICAL

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

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Philippe Subrin – Vice President, Swiss Operations

AUTHORIZATION

2018/09/20

Evelyn De La Vega
Director of Regulatory Affairs

Date

Declaration of Conformity

STAAR® SURGICAL

Class IIb Products

PRODUCTION SITE	MODELS	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	**Preloaded Silicone Intraocular Lenses** KS-3Ai	10 April 2006	Active

Declaration of Conformity

STAAR® SURGICAL

Class IIb Products

INACTIVE MODELS

PRODUCTION SITE	MODELS	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	**Elastic Intraocular Lenses**	
	AA4203	Inactive
	AA4203F	Inactive
	AA4203V	Inactive
	AA4203VF	Inactive
	AA4204VF	Inactive
	AA4204VL	Inactive
	AA4207VF	Inactive
	Elastic Intraocular Lenses with Toric Optic	
	AA4203T	Inactive
	AA4203TF	Inactive
	AA4203TL	Inactive

Declaration of Conformity

STAAR® SURGICAL

Class IIb Products

INACTIVE MODELS

PRODUCTION SITE	MODELS	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	**Elastimide Intraocular Lenses**	
	AQ1016	Inactive
	AQ2003	Inactive
	AQ2010	Inactive
	AQ2013	Inactive
	AQ1016V	Inactive
	AQ2003V	Inactive
	AQ2010V	Inactive
	AQ2017V	Inactive
	AQ5010V	Inactive
	Preloaded Silicone Intraocular Lenses	
	KS-1	Inactive
	KS-3	Inactive

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.

Declaration of Conformity

STAAR® SURGICAL

Class IIb Products

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.