Declaration of Conformity

STAAR® SURGICAL

Class IIa Products

CONFORMITY ASSESSMENT

Class IIa, Rule 6
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

E De La Vega 2018/09/20

Evelyn De La Vega Date
Director of Regulatory Affairs

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Class IIa 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	**MicroSTAAR Injector System**		
	MSI-Indigo-P	4 January 2006	Active
	MSI-PF	16 November 1998	Active
	MSI-TF	16 November 1998	Active
	MSI-TM	16 November 1998	Active
	MSI-PM	16 November 1998	Active
	MicroSTAAR Injector System Plungers		
	FTP	16 November 1998	Active
	FTP-Indigo	16 November 1998	Active
	MicroSTAAR Injector System Cartridges		
	SFC 25	12 March 2013	Active
	SFC 45	12 March 2013	Active

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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	**MicroSTAAR Injector System**	
	MSI-TD	Inactive
	MSI-PD	Inactive
	MSI-TS	Inactive
	MSI-PS	Inactive
	MSI-P1	Inactive
	MSI-TR	Inactive
	MSI-PR	Inactive

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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	**MicroSTAAR Injector System Cartridges**	
	MTC-45	Inactive
	MTC-45s	Inactive
	MTC-45b	Inactive
	MTC-45LP	Inactive
	MTC-60b	Inactive
	SFC-25s	Inactive
	SFC-45s	Inactive
	ST-45	Inactive
	ST-45s	Inactive
	ST-45b	Inactive
	ST-45VS	Inactive
	ST-60	Inactive
	AQ2.8s	Inactive
	MTC-60c	Inactive
	SST-45s	Inactive
	CQ	Inactive
	AQ	Inactive
	MTC 60C FP	Inactive
	SFC 25 FP	Inactive
	SFC 45 FP	Inactive

Class IIa Products

Revision History

Revision A

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

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

Revision B

Class IIa 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.

End date of 14 December 2010 was given to cartridge models SFC 25 FP and SFC 45 FP.

Revision C

Class IIa Declaration of Conformity – Rev C: 2012/03/08

End date of 14 December 2010 was removed from cartridge models SFC 25 FP and SFC 45 FP.

Revision D

Class IIa Declaration of Conformity – Rev D: 2012/04/02

Revision history added to Declaration of Conformity.

Revision E

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

SFC 25 and SFC 45 added to the Monrovia production site.

Revision F

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

Classification rule from MDD added.

Revision G

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

STAAR Japan was removed as a production site; SFC 25 and SFC 45 cartridges are no longer manufactured at Japan location, and all remaining inventory has been sold.

Class IIa Products

Revision H

Class IIa Declaration of Conformity – Rev H: 2015/05/27

Add the status "still active" for SFC 25 and SFC 45 that were previously omitted.

Revision I

Class IIa Declaration of Conformity – Rev I: 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 J

Class IIa Declaration of Conformity – Rev J: 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 K

Class IIa Declaration of Conformity – Rev K: 2016/11/14

Document has been updated to reflect the organizational change of the STAAR Monrovia Quality Assurance from Julie Papp to Philip Tsung. Other changes are administrative edits, including adding inactive models for record, updating Monrovia fax number, formatting adjustment, and updating company logo.

Revision L

Class IIa Declaration of Conformity – Rev L: 2017/03/17

Document has been updated to reflect the currently commercialized MSI Delivery System Injectors, Foam Tip Plungers, and Cartridges. The MSI-TM, MSI-PM, MSI-TR, MSI-PR, MTC-60c FP, SFC-25 FP, and SFC-45 FP will no longer be commercialized in the EU.

Revision M

Class IIa Declaration of Conformity – Rev M: 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 N

Class IIa Declaration of Conformity – Rev N: 2018/02/20

Recent approvals: Alternative autoclave, alternative packaging sealer.

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Revision O

Class IIa Declaration of Conformity – Rev O: 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 the status of MSI-TM and MSI-PM from Inactive to Active, Authorized representative from Michelle Andres to Philippe Subrin.