5900 Optical Court
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T: 408 754 2000, F: 408 754 2505

www.stryker.com

stryker®

Endoscopy

DECLARATION OF CONFORMITY

European Medical Device Directive 93/42/EEC

DoC Number: DECL10064, Rev. T

Manufacturer:	EC Authorized Representative	Registration Number and Report Number
STRYKER ENDOSCOPY 5900 Optical Court San Jose, CA 95138 USA Tel: (408) 754 2000 Fax: (408) 754 2505	EC REP **Stryker European Operations B.V.** Herikerbergweg 110 Amsterdam 1101 CM Netherlands	Registration Number: *HD 60148074 0001* Single Registration Number of the Manufacturer: *N/A* Single Registration Number of the European Authorized Representative: *N/A*

Product Family Name**: (See Annex: Product List)**

Product Class and Rule**: (See Annex: Product List)**

(1) We, Stryker Endoscopy, declare under our sole responsibility that the products specified in *Annex: Product List* are in conformity with the ***Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Annex II, Article 3, Full Quality Assurance System Medical Devices***.

Certificate delivered by TUV Rheinland, LGA Products GmbH, Tillystraße 2, 90431 Nuremberg, Germany, Notified Body Identification Number 0197, in accordance with Annex II, excluding Section 4, Council Directive 93/42/EEC.

(2) We declare, under our sole responsibility, that the products specified in the Annex- Product list also conform to the following regulations and directives. All supporting information is retained under the control of the Legal Manufacturer.

- IEC 63000, Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances; RoHS2 Directive, 2011/65/EU and the RoHS3 Delegated Directive, 2015/863/EU (where appropriate). This statement is applicable only to those part numbers in the annexed product list for which RoHS is applicable.
- Radio Equipment Directive 2014/53/EU established under Article 3 and Article 17. This statement is applicable only to those part numbers in the annexed product list for which Radio Equipment Directive is applicable.

Issue date: September 14, 2020

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Effective date: 27-May-2020
Place of issue: San Jose CA USA

Signed for on behalf of the company by:

Date September 14, 2020 Name of Signee
Kimberly Lynch
Senior Regulatory Manager, Post Market and International

This declaration is valid until: 26-May-2025

Annex – Product List

The following list identifies the products by Catalogue number:

Product Family Name: CrossFlow Arthroscopy Pump and Tube Sets

Catalogue Number	Product Name	Technical File/ Documentation	Product Class and Rule
0450000000 [1,2]	CrossFlow® Integrated Arthroscopy Pump	TF10105	Class IIa, Rule 11
0450-000-100	CrossFlow® Inflow Cassette Tubing	TF10105	Class IIa, Rule 2
0450-000-200 [2]	CrossFlow® Outflow Cassette Tubing	TF10105	Class IIa, Rule 2
0450-000-300	CrossFlow® Integrated Cassette Tubing	TF10105	Class IIa, Rule 2
0450000500 [2]	CrossFlow® Footswitch	TF10105	Class IIa, Rule 11
0450-000-125 [2]	CrossFlow® Patient-Use Tubing	TF10105	Class IIa, Rule 2
0450-000-115	CrossFlow® Day-Use Inflow Cassette Tubing	TF10105	Class IIa, Rule 2

[1] Radio Equipment Directive, 2014/53/EU is applicable.
[2] RoHS2 Directive, 2011/65/EU compliant.

Refer to the Technical File/ Documentation for Intended Purpose and List of Applied Standards of the device.