

DECLARATION OF CONFORMITY

European Medical Device Directive 93/42/EEC

DoC Number: DECL10026, Rev. V

<u>Manufacturer:</u>	<u>EC Authorized Representative</u>	<u>Registration Number and Report Number</u>
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: <i>HD 60148074 0001</i> Single Registration Number of the Manufacturer: <i>N/A</i> Single Registration Number of the European Authorized Representative: <i>N/A</i>

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.

Issue date: September 14, 2020

5900 Optical Court
San Jose, CA 95138
T: 408 754 2000, F: 408 754 2505

www.stryker.com

stryker®

Endoscopy

Effective date: 27-May-2020

Place of issue: San Jose, California USA

Signed for on behalf of the company by:



Date

September 14, 2020

Name of Signee

Kimberly Lynch

Regulatory Affairs 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: Suction Irrigator and Accessories

Pumps

Catalogue Number	Product Name	Technical File/ Documentation	Product Class and Rule
250-070-540	StrykeFlow [®] Pressure System Disposable Suction/Irrigator, Dual Spike Tubing	TF012	Class IIa, Rule 11
250-070-500	StrykeFlow [®] 2 Disposable Suction/Irrigator without Disposable Tip	TF012	Class IIa, Rule 11
0250070601	AHTO [®] 2 Irrigation Pump	TF012	Class IIa, Rule 11

Tuberset

Catalogue Number	Product Name	Technical File/ Documentation	Product Class and Rule
250-070-640	AHTO [®] Disposable Suction/Irrigator Tube Set, Dual Spike	TF012	Class IIa, Rule 2
250-070-530	StrykeFlow [®] Pressure System Disposable Suction/Irrigator, Single Spike Tubing	TF012	Class IIa, Rule 2
250-070-600	AHTO [®] Disposable Suction/Irrigator Tube Set	TF012	Class IIa, Rule 2
250-070-419	StrykeFlow [®] Dual Irrigation Adapter, Disposable	TF012	Class IIa, Rule 2

Accessories (Tips, Guides)

Catalogue Number	Product Name	Technical File/ Documentation	Product Class and Rule
0250-070-437	StrykeFlow [®] Reusable Suction Irrigation Tip, Aspiration Needle, Metal Finish, 5.0 mm × 32 cm	TF012	Class IIa, Rule 7
0250-070-472	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, 2-Hole, Metal Finish, 2.0 mm × 32 cm	TF012	Class IIa, Rule 7
0250-070-483	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Non-Reflective Finish, 5.0 mm × 32 cm	TF012	Class IIa, Rule 7
0250-070-484	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Non-Reflective Finish, 10 mm × 32 cm	TF012	Class IIa, Rule 7
0250-070-485	StrykeFlow [®] Reusable Suction Irrigation Tip, Pool Suction, Non-Reflective Finish, 10 mm × 32 cm	TF012	Class IIa, Rule 7
0250-070-486	StrykeFlow [®] Reusable Suction Irrigation Tip, Pool Suction, Non-Reflective Finish, 5.0 mm × 32 cm	TF012	Class IIa, Rule 7
0250-070-487	StrykeFlow [®] Reusable Suction Irrigation Tip, Hydrodissection, Non-Reflective Finish, 5.0 mm × 32 cm	TF012	Class IIa, Rule 7

Catalogue Number	Product Name	Technical File/ Documentation	Product Class and Rule
0250-070-488	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Non-Reflective Finish, 5 x 45 cm	TF012	Class IIa, Rule 7
0250-070-489	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Non-Vented, Non-Reflective Finish, 5.0 mm x 32 cm	TF012	Class IIa, Rule 7
0250-070-490	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Metal Finish, 3. X 32 cm	TF012	Class IIa, Rule 7
0250-070-491	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Non-Vented, Metal Finish, 3. X 32 cm	TF012	Class IIa, Rule 7
250-070-505	StrykeFlow [®] Disposable Suction /Irrigation Tip, Standard, Vented, Metal Finish, 5.0 mm x 32 cm	TF012	Class IIa, Rule 7
0250-070-492	StrykeFlow [®] Reusable Suction Irrigation Tip, Stone Scooper, Metal Finish, 10 mm x 32 cm	TF012	Class IIa, Rule 7
250-070-620	AHTO [®] Disposable Suction/Irrigator Tube Set with Tip	TF012	Class IIa, Rule 7
250-070-520	StrykeFlow [®] 2 Disposable Suction/Irrigator with Disposable Tip	TF012	Class IIa, Rule 7
0250-070-402	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Metal Finish, 5.0 mm x 28 cm	TF012	Class IIa, Rule 7
0250-070-403	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Metal Finish, 5.0 mm x 32 cm	TF012	Class IIa, Rule 7
0250-070-404	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Metal Finish, 10 mm x 32 cm	TF012	Class IIa, Rule 7
0250-070-405	StrykeFlow [®] Reusable Suction Irrigation Tip, Pool Suction, Metal Finish, 10 mm x 32 cm	TF012	Class IIa, Rule 7
0250-070-406	StrykeFlow [®] Reusable Suction Irrigation Tip, Pool Suction, Metal Finish, 5.0 mm x 32 cm	TF012	Class IIa, Rule 7
0250-070-407	StrykeFlow [®] Reusable Suction Irrigation Tip, Hydrodissection, Metal Finish, 5.0 mm x 32 cm	TF012	Class IIa, Rule 7
0250-070-408	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Metal Finish, 5. X 45 cm	TF012	Class IIa, Rule 7
0250-070-409	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Non-Vented, Metal Finish, 5.0 mm x 32 cm	TF012	Class IIa, Rule 7
0250-070-411	StrykeFlow [®] Reusable Suction Irrigation Tip, Standard, Vented, Metal Finish, 5.0 mm x 24 cm	TF012	Class IIa, Rule 7
250-070-413	StrykeFlow [®] Laser Fiber Guide	TF012	Class IIa, Rule 7

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