

**Endoscopy** 

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## Declaration Of Conformity European Medical Device Directive 93/42/EEC

DoC Number: DECL10077, Rev. F

Manufacturer:	EC Authorized Representative	Registration Number and Report Number
STRYKER ENDOSCOPY 5900 Optical Court	EC REP	Registration Number: HD 60104853 0001
San Jose, CA 95138 USA	Stryker European Operations B.V.	Report Number: 31492313 001
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	1101 CM	
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<u>Product Family Name</u>: (See Annex: Product List)

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

- (1) The products specified in Annexed-Product list, conform to the product(s) covered by "EC Directive 93/42/EEC 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 Directives 93/42/EEC of 14 June 1993 concerning medical devices.
- (2) The products listed in Annex-Product list conform to the harmonized standard EN 50581, and comply with the RoHS2 Directive, 2011/65/EU, and the RoHS3 Delegated Directive, 2015/863/EU (where applicable). All supporting information is retained under the control of the legal manufacturer

Issue date: 28-Sep-2018

Signed for and behalf of Stryker Endoscopy by:

Date 28 Sept 2018 Name of Signee Kimberly Lynch

Regulatory Compliance Manager

Kimlerly Lynch

This declaration is valid until: 01-Oct-2020



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## <u>Annex – Product List</u>

The following list identifies the products by Catalogue number .

Product Family Name: Arthroscopic Cannula (J-Lock Cannulas)

Catalogue Number	Product Name	Product Class and Rule
0502-711-530	Cannula, 1 Rotating Stopcock, J-Lock, 2.8 mm	Class IIa, Rule 7
0502-711-550	Cannula, 1 Fixed Stopcock, J-Lock, 2.8 mm	Class IIa, Rule 7
0502-711-560	Cannula, 2 Rotating Stopcocks, J-Lock, 2.8 mm	Class IIa, Rule 7
0502-712-530	Cannula, 1 Rotating Stopcock, J-Lock, 2.9 mm	Class IIa, Rule 7
0502-713-530	Cannula, 1 Rotating Stopcock, J-Lock, 3.2 mm	Class IIa, Rule 7
0502-713-550	Cannula, 1 Fixed Stopcock, J-Lock, 3.2 mm	Class IIa, Rule 7
0502-713-560	Cannula, 2 Rotating Stopcocks, J-Lock, 3.2 mm	Class IIa, Rule 7
0502-713-540	Cannula, 2 Fixed Stopcocks, J-Lock, 3.2 mm	Class IIa, Rule 7
0502-714-560	Cannula, 2 Rotating Stopcocks, J-Lock, 4.0 mm	Class IIa, Rule 7
0502-714-540	Cannula, 2 Fixed Stopcocks, J-Lock, 4.0 mm	Class IIa, Rule 7
0502-714-550	Cannula, 1 Fixed Stopcock, J-Lock, 4.0 mm	Class IIa, Rule 7
0502-714-530	Cannula, 1 Rotating Stopcock, J-Lock, 4.0 mm	Class IIa, Rule 7