

# DECLARATION OF CONFORMITY

## European Medical Device Directive 93/42/EEC

DoC Number: DECL10096, Rev. F

<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	<b>EC REP</b> <b>Stryker European Operations</b> <b>B.V.</b> Herikerbergweg 110 Amsterdam 1101 CM Netherlands	Registration Number: SX 60132127 0001  Report Number: 31792498 005

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

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

(1) According to Annex VII of the Council Directive 93/42/EEC concerning Medical Devices, we declare under our sole responsibility that the distributed CE marked products specified in the Annexed-Product list, meet the provisions of the Council Directive 93/42/EEC concerning medical devices. This declaration is supported by Quality System Certificate

(2) The products listed in the 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: 26-Sep-2018

Signed for and behalf of Stryker Endoscopy by:



Date: 02-Oct-2018

Name of Signee  
Kimberly Lynch  
Regulatory Compliance Manager

This declaration is valid until: 24-Aug-2021

### Annex – Product List

The following list identifies the products by Catalogue number.

**Product Family Name:** Arthroscopic Cannula (Obturators and Trocars)

Catalogue Number	Product Name	Product Class and Rule
0502-711-500	Pencil tip obturator for 2.8mm cannula, J-Lock	Class I, Rule 6
0502-711-510	Blunt tip obturator for 2.8mm cannula, J-Lock	Class I, Rule 6
0502-712-500	Pencil tip obturator for 2.9mm cannula, J-Lock	Class I, Rule 6
0502-713-500	Pencil tip obturator for 3.2mm cannula, J-Lock	Class I, Rule 6
0502-713-510	Blunt tip obturator for 3.2mm cannula, J-Lock	Class I, Rule 6
0502-714-500	Pencil tip obturator for 4.0mm cannula, J-Lock	Class I, Rule 6
0502-714-510	Blunt tip obturator for 4.0mm cannula, J-Lock	Class I, Rule 6
0502-711-520	Trocar for 2.8mm cannula, J-Lock	Class I, Rule 6
0502-712-520	Trocar for 2.9mm cannula, J-Lock	Class I, Rule 6
0502-713-520	Trocar for 3.2mm cannula, J-Lock	Class I, Rule 6
0502-714-520	Trocar for 4.0mm cannula, J-Lock	Class I, Rule 6