571 Silveron Blvd.
Flower Mound, TX 75028 USA
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www.stryker.com

VĂN PHÒNG ĐẠI DIỆN STRYKER SALES CORPORATION TẠI TP. HỒ CHÍ MINH (HOA KỲ)

Digitally signed by VĂN PHÒNG ĐẠI DIỆN STRYKER SALES CORPORATION TẠI TP. HỒ CHÍ MINH (HOA KỲ)
Date: 2018.06.25 10:58:48 +07'00'

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

DoC Number: DECL10242, Rev. A

Manufacturer:	EC Authorized Representative	Registration Number and Report Number
Stryker Communications 571 Silveron Blvd. Flower Mound, TX 75028 USA Tel: (972)-410-7100 Fax: (972)-410-7001	EC REP **Stryker European Operations B.V.** Herikerbergweg 110 Amsterdam 1101 CM Netherlands	Registration Number: *SX* 60118770 0001 Report Number: 31191485 010

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, which apply to them.

Conformity assessment was performed according to **Annex VII**.

This declaration is supported by Quality System Certificate for the products concerned. The conformity to quality assurance set out in the said EN ISO 13485:2012/AC:2012 Conformity Certificate number SX 60118770 0001 issued and delivered by TUV Rheinland, LGA Products GmbH, Tillystraße 2, 90431 Nuremberg, Germany.

(2) We declare, under our sole responsibility, that the products specified in the annexed product list conform to the harmonized standard EN 50581, and thereby comply with the RoHS2 Directive, 2011/65/EU. It should be noted that this statement is applicable to only those part numbers in the annexed product list for which the RoHS2 Directive, 2011/65/EU is applicable.

Issue date: 08 May 2017

Signed for and behalf of Stryker Communications by:

Date 8 MAY 2017

Adam Gorzeman
Regulatory Affairs Manager

This declaration is valid until: *19 SEP 2017*

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Annex – Product List

This product list belongs to the Declaration of Conformity identified by Stryker Endoscopy and specifies the CE marked products concerned that Stryker Endoscopy intends to distribute in conformity with the provisions of Council Directive 93/42/EEC concerning medical devices and Council Directive 2011/65/EU concerning electrical and electronic equipment.

The following list identifies the products by Catalogue number and type.

Product Family Name: *Strykecam HD for F-Gen*

Catalogue Number	Product Name	Product Class and Rule
P31858	**Strykecam HD for F-Gen**	**Class I, Rule 1 & 12**
P30340	**HD Camera External Communication Interface Box**	**Class I, Rule 1 & 12**
P22059	**Hi-Def Camera Decoder Assembly**	**Class I, Rule 1 & 12**