EC DECLARATION OF CONFORMITY

Manufacturer:	ELLA-CS, s.r.o. Milady Horákové 504/45, Třebeš 500 06 Hradec Králové Czech Republic
Product:	**SX-ELLA Stent Esophageal HV (HV Stent Plus)** *Self-expandable esophageal metallic stent in the delivery system* *(Non-active implantable medical device)*
Classification:	a) class: II b b) rule: 8
Conformity assessment route:	Annex II to Council Directive 93/42/EEC amended by Directive 2007/47/EC

Catalogue numbers:		
	019-09S-20-085	019-09S-20-085-O
	019-09S-20-110	019-09S-20-110-O
	019-09S-20-135	019-09S-20-135-O
	019-09S-20-150	019-09S-20-150-O

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and Directive 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:

- **EN ISO 13485:2012** Medical devices – Quality management systems – Requirements for regulatory purposes
- **EN ISO 14630:2012** Non-active surgical implants – General requirements
- **EN ISO 14971:2012** Medical devices – Application of risk management to medical devices
- **EN ISO 10993-1:2009/AC:2010** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- **EN ISO 10993-5:2009** Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- **EN ISO 10993-7:2008/AC:2009** Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

- **EN ISO 14644-1:2015** Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration

- **EN ISO 14644-2:2015** Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

- **EN ISO 11135:2014** Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices

- **EN ISO 11737-1:2006/AC:2009** Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products

- **EN 556-1:2001/AC:2006** Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices

- **EN ISO 11138-1:2017** Sterilization of health care products - Biological indicators - Part 1: General requirements

- **EN ISO 11138-2:2017** Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

- **EN ISO 11607-1:2017** Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

- **EN 1041:2008+A1:2013** Information supplied by the manufacturer of medical devices

- **EN ISO 15223-1:2016** Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

- **MEDDEV 2.12/1** in the current version: Guidelines on a medical devices vigilance system

Notified Body: Electrotechnical Testing Institute
Pod lisem 129
Prague 8 – Troja
Czech Republic
Notified body No. 1014

EC Certificate: MED 170034 – issued on June 29, 2017; valid until June 28, 2022

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