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 Degradable BD (BD Stent)
(Non-active implantable medical device)

Classification:

a) class: III
b) rule: 8

Conformity assessment route:

Annex II to Council Directive 93/42/EEC amended by Directive 2007/47/EC

Catalogue numbers:

019-10A-23/18/23-060	019-10A-28/23/28-060
019-10A-23/18/23-080	019-10A-28/23/28-080
019-10A-23/18/23-100	019-10A-28/23/28-100
019-10A-25/20/25-060	019-10A-31/25/31-060
019-10A-25/20/25-080	019-10A-31/25/31-080
019-10A-25/20/25-100	019-10A-31/25/31-100
	019-10A-31/25/31-135

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 10993-3:2014** Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- **EN ISO 10993-5:2009** Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

- **EN ISO 10993-6:2016** Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

- **EN ISO 10993-7:2008/AC:2009** Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

- **EN ISO 10993-9:2009** Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products

- **EN ISO 10993-10:2013** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

- **EN ISO 10993-11:2009** Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

- **EN ISO 10993-13:2010** Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices

- **EN ISO 10993-16:2010** Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables

- **EN ISO 10993-18:2009** Biological evaluation of medical devices - Part 18: Chemical characterization of materials

- **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 Certificates:

MED 170035 – issued on June 29, 2017; valid until June 28, 2022
MED 170036 – issued on June 29, 2017; valid until June 28, 2022

CE marked since:

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