EC DECLARATION OF CONFORMITY

Manufacturer: ELLA–CS, s.r.o.
Milady Horákové 504/45 Třebeš
500 06 Hradec Králové 6
Czech Republic

Product: **SX-ELLA Stent Danis (Danis Stent)**
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

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 25539-1:2009 Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses
- 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
- 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
- EN ISO 14644-2:2015 Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
- EN ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN ISO 11737-1:2006 Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- EN 556-1:2001 Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices

- EN ISO 11138-1:2006 Sterilization of health care products – Biological indicators – Part 1: General requirements
- EN ISO 11138-2:2009 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
- EN ISO 11607-1:2009/A1:2014 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN 1041+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

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