ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

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ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT D'ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 170034

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **ELLA-CS, s.r.o.**
Milady Horákové 504/45, Třebeš , 500 06 Hradec Králové, Czech Republic

for design, manufacturing and final inspection of medical device(s)

Stents Systems for Gastrointestinal Tract, Class IIb, see annex

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **604246-02 of 27.6.2017**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 29.06.2017 with validity until 28.06.2022
The validity of this Certificate is limited until: 28.06.2022

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129, 171 02 Praha 8 - Troja

29.06.2017

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

* C E R / M E D 1 7 0 0 3 4 *

604246-02

Stents Systems for Gastrointestinal Tract, Class IIb

SX-ELLA Stent Biliary (Nitinella Plus*)

SX-ELLA Stent Biliary (Nitinella Plus*) – B

SX-ELLA Stent Pyloroduodenal (Enterella*)

SX-ELLA Stent Colorectal (Enterella*)

SX-ELLA Stent Esophageal (Flexella Plus*) PUSH

SX-ELLA Stent Esophageal (Flexella Plus*) PULL

SX-ELLA Stent Esophageal HV (HV Stent Plus*)

Esophageal Stent Danis Seal (Danis Seal*)

SX-ELLA Stent Danis (Danis Stent*)

FerX-ELLA Esophageal Stent (Boubella*)

FerX-ELLA Esophageal Stent (Boubella-E*)

End of the list

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Pod lisem 129/2, 171 02 Praha 8 - Troja

The Electrotechnical Testing Institute Certification Body No. 3004 for certification of management systems, accredited by the Czech Accreditation Institute, o.p.s. in accordance with ČSN EN ISO/IEC 17021-1, grants the

CERTIFICATE

No.: 8180128

for the Quality Management System in accordance with

EN ISO 13485:2016

to the Firm

ELLA-CS, s.r.o.

Milady Horákové 504/45, Třebeš, 500 06 Hradec Králové, Czech Republic

in localities: Work place: Šárovcová 1273, 503 46 Třebechovice pod Orebem
Šimkova 870, 500 03 Hradec Králové, auxiliary operation in the street Heyrovského.

because it ascertained that the Quality Management System of the Firm in localities and processes:

Design and Development, Production, Sale and Distribution of Medical Devices in these categories:
- **Stents for Gastrointestinal Tract**
- **Biodegradable Stents**
- **Stent Extractors**

Distribution of Guide Wire RevoWave
Production of Neurosurgical Medical Devices

complies with all requirements of the above mentioned Standard documented by the Report No.: 803432-01 of 03.12.2018

The validity of the Certificate is limited till: 02.12.2021

The Certified Organization is subject to annual check-ups carried out by the Certification Body. Any change within the organization concerning the certification shall be followed up and approved by the Electrotechnical Testing Institute. The validity of this Certificate may be suspended or cancelled in the event of non-compliance with the Standard on the basis of which the Certificate was issued.

Certificate granted: 03.12.2018

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

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803432-01