

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 702408**

Issued To:
ELLA-CS, s.r.o.
Milady Horákové 504/45
Trebes
Hradec Králové
500 06
Czech Republic

In respect of:

Design, development and manufacture of sterile biliary and esophageal stents and sterile stent extractors.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-08-10**

Date: **2020-08-10**

Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 702408

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Number	Device Name	Intended purpose per IFU
Class IIb		
GMDN: 61751	SX-ELLA Stent Esophageal HV (HV Stent Plus)	Indicated for palliative treatment of malignant dysphagia, for sealing malignant tracheoesophageal or bronchoesophageal fistula. The device can be temporarily implanted in patients with refractory benign esophageal strictures.
	SX-ELLA Stent Esophageal (Flexella Plus) PULL	
	SX-ELLA Stent Danis (Danis stent)	SX-ELLA Stent Danis is intended to stop acute refractory bleeding from esophageal varices
GMDN : 43566	SX-ELLA Stent Biliary (Nitinella Plus)	Indicated for palliative bile drainage in case of biliary obstruction resulting from biliary, pancreatic, periampullary, or metastatic tumors that are unresectable due to tumor stage or the patient's poor surgical condition.
GMDN : 43691	SX-ELLA Stent Biliary - B (Nitinella Plus – B)	
Class IIa		
GMDN : 58295 NBOG : MD0106	Extractor for SX-ELLA Stents Esophageal (ELLA Extractor)	Intended to retrieval of defined range of esophageal SX-ELLA stents

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Page 2 of 2

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