By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 752864 R000

Manufacturer: ELLA-CS, s.r.o.

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Czech Republic

Single Registration Number: CZ-MF-000013402

Digitally signed by Bunic Gheorghe
Date: 2025.05.25 15:47:22 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-08-22**

Current Issue Date: **2024-08-22**

Starting Validity Date: **2024-08-22**

Expiry Date: **2029-08-21**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

ELLA-BD Stent Biliary THP is designed for the treatment of benign bile duct strictures.

Type (codes as per (EU) 2017/2185): MDN1104

Classification: Class III Implantable

Device Name	Model	Catalogue Number	Description: Stent Diameter (mm) x Stent length (mm)	Basic UDI-DI
ELLA-BD Stent Biliary THP	019-15-08-030	019-15-08-030	8 x 30	08591794BILB15JX
	019-15-08-040	019-15-08-040	8 x 40	
	019-15-08-050	019-15-08-050	8 x 50	
	019-15-08-060	019-15-08-060	8 x 60	
	019-15-08-070	019-15-08-070	8 x 70	
	019-15-08-080	019-15-08-080	8 x 80	
	019-15-10-030	019-15-10-030	10 x 30	
	019-15-10-040	019-15-10-040	10 x 40	
	019-15-10-050	019-15-10-050	10 x 50	
	019-15-10-060	019-15-10-060	10 x 60	
	019-15-10-070	019-15-10-070	10 x 70	
	019-15-10-080	019-15-10-080	10 x 80	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3481667	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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