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EU DECLARATION OF CONFORMITY

Manufacturer:

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

Single registration number: **CZ-MF-000013402**

Basic UDI-DI: **08591794BILB15JX**

Product trade name: **ELLA-BD Stent Biliary THP**
(Non-active implantable medical device)

Model	Nominal (Relaxed) Diameter of Stent Body [mm]	Nominal (Relaxed) Length of Stent [mm]	Catalogue number:
15	8	30	019-15-08-030
		40	019-15-08-040
		50	019-15-08-050
		60	019-15-08-060
		70	019-15-08-070
		80	019-15-08-080
	10	30	019-15-10-030
		40	019-15-10-040
		50	019-15-10-050
		60	019-15-10-060
		70	019-15-10-070
		80	019-15-10-080

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

Classification acc. to Annex VIII:

a) class: III - implantable
b) rule: 8

Conformity assessment route: Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

We herewith declare that this EC Declaration of Conformity was issued under our sole responsibility and the above mentioned medical devices conform to the General safety and performance requirements set out in Annex I of the Regulation (EU) 2017/745 of

the European Parliament and of the Council of 5 April 2017 on medical devices. All supporting documentation is retained under the premises of the manufacturer.

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Kaynesplein 9, 1066 EP
Amsterdam, Netherlands
Notified body No. 2797

EU Certificates: MDR 752864 – issued on 22-08-2024; valid until 21-08-2029

CE marked since: Date: 10-09-2024
Lot Number: P24090085-01 (2 pieces)

Place of issue: Hradec Králové, Czech Republic
Date of issue: 10-09-2024

Doc. RNDr. PhMr. Karel Volenec, CSc.
Digitally signed by Doc. RNDr. PhMr. Karel Volenec, CSc.
Date: 2024.09.10 15:45:31 +02'00'

Assoc. Prof. Karel Volenec, Ph.D.
Person Responsible for Regulatory Compliance of ELLA-CS, s.r.o.