

EU Technical Documentation Assessment Certificate

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

MDR 752864 R000

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

Address:

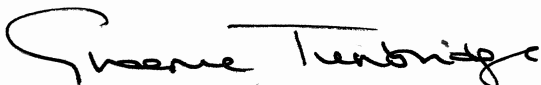
Milady Horákové 504/45
Třebeš
Hradec Králové
500 06
Czech Republic

Single Registration Number: CZ-MF-000013402

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: **2025-12-09**

Starting Validity Date: **2025-12-09**

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

...making excellence a habit.™

Page 1 of 3

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.

EU Technical Documentation Assessment Certificate

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

MDR 752864 R000

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

Risk 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 | |

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

Current Issue Date: **2025-12-09**

Starting Validity Date: **2025-12-09**

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

...making excellence a habit.™

Page 2 of 3

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.

EU Technical Documentation Assessment Certificate

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

MDR 752864 R000

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 |
|------------|------------------|---|
| 2024-08-22 | 3481667 | Issued |
| 2024-11-21 | 30268715 | Amended - Shelf-life extension from one year to two years |
| 2025-07-31 | 30472444 | Amended - Addition of Manufacturing site for delivery systems |
| Current | 30605592 | Amended - Crucial supplier addition for delivery device component |



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

Current Issue Date: **2025-12-09**

Starting Validity Date: **2025-12-09**

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

...making excellence a habit.™

Page 3 of 3

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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
A Member of the BSI Group of Companies.