

## DECLARATION OF CONFORMITY

- Name of Manufacturer** : Shaili Endoscopy
- Address of Manufacturer** : Plot No.: 210 & 213, Padara Jambusar Road, Village: Dabhasa,  
Tal.: Padra, Dist.: Vadodara-391440 Gujarat, INDIA.  
**E-mail:** [drparesh@shailiendoscopy.com](mailto:drparesh@shailiendoscopy.com)  
**Web Site:** [www.shailiendoscopy.com](http://www.shailiendoscopy.com)
- Name & Address of European Authorized Representative** : OBELIS S.A  
Bd. General Wahis 53  
B-1030 Brussels, Belgium  
Email: [mail@obelis.net](mailto:mail@obelis.net)  
Web site: <http://www.obelis.net>
- Notified Body Name and Number** : DNV & 2460
- Product Type** : Multi Band Ligator
- Product Model** : As Per Annexure A.
- Product Intended Use** : Multi Band Ligator used for endoscopic ligation of Esophageal varices at or above gastro Esophageal junction and colonic varices.
- Product Classification** : Multi Band ligator has been assessed with respect to the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended.  
In view of the above and pursuant to Article 5 of the MDD, the applicable classification rules for these devices are Annex IX, Chapter II, Section 2.1 (rule 5). These rules lead to classifying Multi Band Ligator as class IIa medical devices.
- Standards Applied** : MDD 93/42/EEC as amended by 2007/47/EC, MDR 2017, EN ISO 10993-1:2009 & applicable series of ISO 10993, EN ISO 14971:2012/ISO 14971:2019, EN ISO 13485:2016, EN 15223-1:2016, EN 1041:2008+A1:2013; EN 62366:2015; EN ISO 11607-1:2009/ISO 11607-1:2019, EN ISO 11607-2:2006/ISO 11607-2:2019, ISO 14644-1:2015; ISO 14644-3:2005/ ISO 14644-3:2019; ISO 14698-1:2003; ISO 14698-2:2003

*We, The Manufacturer, Under Our Sole Responsibility, Herewith Declare That The Stated Medical Devices Meet The Transposition Into National Law, Of The Provisions Of Council Directive 93/42/EEC Of 14 June 1993 Concerning Medical Devices*

**Quality Assurance By:** Rakesh Saroj

**Designation:** Manager QA/RA

**Sign & Date:**

**Location:** Vadodara

Doc. No.: SE/DOC/MBL Rev.05 dt. 01/01/2022

## Annexure A-Product Models

Reference No.:	Product Name	GMDN Code	CE Classification
SBLS-6-F*	BAND LIGATOR SET (With 6 Loaded Bands)	40365	IIa
SBLS-6-O*	BAND LIGATOR SET(With 6 Loaded Bands)	40365	IIa
SBLS-7-F*	BAND LIGATOR SET(With 7 Loaded Bands)	40365	IIa
SBLS-7-O*	BAND LIGATOR SET(With 7 Loaded Bands)	40365	IIa
SBLS-6-P-F*	BAND LIGATOR SET PAEDIATRIC	40365	IIa
SBLS-6-P-O*	BAND LIGATOR SET PAEDIATRIC	40365	IIa
SBL-6-F*	MULTI BAND LIGATOR-BARREL	40365	IIa
SBL-6-O*	MULTI BAND LIGATOR-BARREL	40365	IIa
SBL-7-F*	MULTI BAND LIGATOR-BARREL	40365	IIa
SBL-7-O*	MULTI BAND LIGATOR-BARREL	40365	IIa
SBL-6-P-F*	MULTI BAND LIGATOR - BARREL PAEDIATRIC	40365	IIa
SBL-6-P-O*	MULTI BAND LIGATOR - BARREL PAEDIATRIC	40365	IIa
SBLS-6-C	BAND LIGATOR SET	40365	IIa
SBL-6-C	BARREL	40365	IIa
SBLS-7-C	BAND LIGATOR SET	40365	IIa
SBL-7-C	BARREL	40365	IIa

\* Indicate Length of Thread.

F= 175 cm. for Fujinon Endoscope. O= 155 cm for Olympus / Pentax Endoscope

The highlighted marking under the ordering information is used for endoscopic ligation of colonic varices.

### AMENDMENT HISTORY

Revision No.	Revision Date	Revision Done	Revised By
00	10/07/2017	Initial Version of Declaration of Conformity	QA
01	11/05/2019	Correction made in Notified body name	QA
02	01/07/2020	Applied standards updated in DOC	QA
03	24/06/2021	Correction made in Notified body name	QA
04	21/07/2021	Applied standards updated in DOC	QA
05	01/01/2022	Correction in notified body name & Change EU Representative	QA