

DECLARATION OF CONFORMITY

Name of Manufacturer	: Shaili Endoscopy
Address of Manufacturer	: Plot No.: 210 & 213, Padra Jambusar Road, Village: Dabhasa, Tal.: Padra, Dist.: Vadodara-391440 Gujarat, INDIA. E-mail: drparesh@shailiendoscopy.com Web Site: www.shailiendoscopy.com
Name & Address of European Authorized Representative	: OBELIS S.A Bd. General Wahis 53 B-1030 Brussels, Belgium Email: mail@obelis.net Web site: http://www.obelis.net
Notified Body Number	: 2460
Certificate Number	: 253866-2018-CE-IND-NA-PS Rev.4.0
Product Type	: Biliary Stent & Set
Product Model	: As Per Annexure A.
Product Intended Use	: Biliary Stent is used to drain bile from obstructed biliary duct.
Product Classification	: Biliary stent & Set 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 III, Section 2.1 (rule 5). These rules lead to classifying Biliary Stent & Set as class IIb medical devices.
EMDN code	: G03040301
Basic UDI-DI	: 89041742SEBSS00439
Standards Applied	: MDD 93/42/EEC as amended by 2007/47/EC, Indian MDR 2017, EN ISO 10993-1:2020 & applicable series of ISO 10993, EN ISO 14971:2012/ISO14971:2019, EN ISO 13485:2016, EN 15223-1:2021, EN ISO 20417:2021; EN ISO 11135:2014/A1:2019; IEC 62366-1:2015/A1:2022 ; EN ISO 11138-2:2017; EN ISO 11607-1:2020; EN ISO 11607-2:2020, EN ISO 11737-1:2018 EN ISO 11737-2:2018; EN ISO 14644-1:2015; ISO 14644-2:2015; 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



Annexure A-Product Models

- Where X = STENT Length Increase 1 cm (3, ..., 20 cm) as per customer requirement.

REFERENCE No.	PRODUCT NAME	VARIANTS	CE Classification
SBSS-TEF-5-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PTFE 5FR	IIB
SBSS-PU-5-S-X	BILIARY STENT SET	BILIARY STENTSET FOR STENT STRAIGHT PE 5FR	IIB
SBSS-TEF-7-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PTFE 7FR	IIB
SBSS-PU-7-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PE 7FR	IIB
SBSS-TEF-8.5-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PTFE 8.5FR	IIB
SBSS-PU-8.5-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PE 8.5FR	IIB
SBSS-TEF-10-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PTFE 10FR	IIB
SBSS-PU-10-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PE 10FR	IIB
SBSS-TEF-11.5-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PTFE 11.5FR	IIB
SBSS-PU-11.5-S-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STRAIGHT PE 11.5 FR	IIB
SBSS-TEF-8.5-T-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT TREE TYPE PTFE 8.5FR	IIB
SBSS-TEF-10-T-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT TREE TYPE PTFE 10FR	IIB
SBSS-TEF-11.5-T-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT TREE TYPE PTFE 11.5FR	IIB
SBSS-PU-5-DP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT DOUBLE PIGTAIL PE 5FR	IIB
SBSS-PU-7-DP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT DOUBLE PIGTAIL PE 7FR	IIB
SBSS-PU-8.5-DP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT DOUBLE PIGTAIL PE 8.5FR	IIB
SBSS-PU-10-DP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT DOUBLE PIGTAIL PE 10FR	IIB
SBSS-PU-11.5-DP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT DOUBLE PIGTAIL PE 11.5FR	IIB
SBSS-PU-5-SP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT SINGLE PIGTAIL PE 5FR	IIB
SBSS-PU-7-SP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT SINGLE PIGTAIL PE 7FR	IIB

SBSS-PU-8.5-SP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT SINGLE PIGTAIL PE 8.5FR	Iib
SBSS-PU-10-SP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT SINGLE PIGTAIL PE 10FR	Iib
SBSS-PU-11.5-SP-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT SINGLE PIGTAIL PE 11.5FR	Iib
SBSS-PU-5-SB-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT S BANDED PE 5FR	Iib
SBSS-PU-7-SB-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT S BANDED PE 7FR	Iib
SBSS-PU-8.5-SB-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT S BANDED PE 8.5FR	Iib
SBSS-PU-10-SB-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT S BANDED PE 10FR	Iib
SBSS-PU-11.5-SB-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT S BANDED PE 11.5FR	Iib
SBSS-PU-5-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PE 5FR	Iib
SBSS-PU-7-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PE 7FR	Iib
SBSS-PU-8.5-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PE 8.5FR	Iib
SBSS-PU-10-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PE 10FR	Iib
SBSS-PU-11.5-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PE 11.5FR	Iib
SBSS-TEF-5-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PTFE 5FR	Iib
SBSS-TEF-7-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PTFE 7FR	Iib
SBSS-TEF-8.5-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PTFE 8.5FR	Iib
SBSS-TEF-10-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PTFE 10FR	Iib
SBSS-TEF-11.5-CS-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT C SHAPE PTFE 11.5FR	Iib
SBSS-TEF-5-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PTFE 5FR	Iib
SBSS-PU-5-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PE 5FR	Iib
SBSS-TEF-7-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PTFE 7FR	Iib
SBSS-PU-7-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PE 7FR	Iib
SBSS-TEF-8.5-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PTFE 8.5FR	Iib

SBSS-PU-8.5-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PE 8.5FR	IIb
SBSS-TEF-10-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PTFE 10FR	IIb
SBSS-PU-10-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PE 10FR	IIb
SBSS-TEF-11.5-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PTFE 11.5FR	IIb
SBSS-PU-11.5-STD-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT STANDARD PE 11.5FR	IIb
SBSS-TEF-5-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PTFE 5FR	IIb
SBSS-PU-5-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PE 5 FR	IIb
SBSS-TEF-7-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PTFE 7FR	IIb
SBSS-PU-7-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PE 7FR	IIb
SBSS-TEF-8.5-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PTFE 8.5FR	IIb
SBSS-PU-8.5-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PE 8.5FR	IIb
SBSS-TEF-10-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PTFE 10FR	IIb
SBSS-PU-10-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PE 10FR	IIb
SBSS-TEF-11.5-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PTFE 11.5FR	IIb
SBSS-PU-11.5-AMST-X	BILIARY STENT SET	BILIARY STENT SET FOR STENT AMSTERDAM PE 11.5FR	IIb

AMENDMENT HISTORY

Revision No.	Revision Date	Revision Done	Revised By
00	10/07/2017	Initial Version of Declaration of Conformity	QA
01	17/05/2018	Standard list Updated	QA
02	11/05/2019	Correction made in Notified body name	QA
03	01/07/2020	Applied standards updated in DOC	QA
04	24/06/2021	Correction made in Notified body name	QA
05	21/07/2021	Applied standards updated in DOC	QA
06	01/01/2022	Correction in notified body name & Change EU Representative	QA
07	26/03/2022	Correction made in notified body name & update applicable Standards	QA
08	28/03/2023	Applied Standards updated in DOC	QA

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