

EC Certificate Full Quality Assurance System

Certificate No.:
253866-2018-CE-IND-NA-PS Rev. 4.0

Project No.:
PRJC-565765-2017-MSL-IND

Valid Until:
08 June 2023

This is to certify that the quality system of:

SHAILI ENDOSCOPY

PLOT NO. 210 & 213, PADRA JAMBUSAR ROAD,
VILLAGE: DABHASA, TAL: PADARA,
Dist: VADODARA – 391440, GUJARAT, INDIA

For design, production and final product inspection/testing of:

Devices for Gastroenterology, Urology

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II
excluding section 4 of Council Directive 93/42/EEC on Medical
Devices, as amended**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.



Place and Date:
Høvik, 22 March 2019



For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2018-06-08
1.0	Active Devices added	2018-08-31
2.0	New devices added	2019-01-11
3.0	New devices added	2019-03-14
4.0	Correction typographical error in device classification (in bold)	2019-03-22

Products covered by this Certificate:

Product Description	Product Name	Class
Biliary Stent	Biliary Stent Straight PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Straight PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Tree Type PTFE (8.5FR, 10FR, 11.5FR) Biliary Stent Double Pigtail PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Single Pigtail PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent S Banded PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent C Shape PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent C Shape PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Standard PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Standard PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Amsterdam PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Amsterdam PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR)	IIb
Biliary Stent Set	Biliary Stent Set Straight PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Set Straight PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Set Tree Type PTFE (8.5FR, 10FR, 11.5FR) Biliary Stent Set Double Pigtail PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Set Single Pigtail PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Set S Banded PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR) Biliary Stent Set C Shape PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR)	IIb



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	Super Stiff Hydra Neg Wire(Sshyneg) 0.035 Angulated Super Stiff Hydra Neg Wire(Sshyneg) 0.035 J Tip Super Stiff Hydra Neg Wire(Sshyneg) 0.038 Straight Super Stiff Hydra Neg Wire(Sshyneg) 0.038 Angulated Super Stiff Hydra Neg Wire (Sshyneg)0.038 J Tip Nitinol Black Guidewire 0.025 Straight Nitinol Black Guidewire 0.025 Angulated Nitinol Black Guidewire 0.025 J Tip Nitinol Black Guidewire 0.032 Straight Nitinol Black Guidewire 0.032 Angulated Nitinol Black Guidewire 0.032 J Tip Nitinol Black Guidewire 0.035 Straight Nitinol Black Guidewire 0.035 Angulated Nitinol Black Guidewire 0.035 J Tip Nitinol Black Guidewire 0.038 Straight Nitinol Black Guidewire 0.038 Angulated Nitinol Black Guidewire 0.038 J Tip Spring Tip Steel Guide Wire - Single Use, SMGW2.0 mm diameter Working length 250cm Stiff Guide Wire 0.035" Straight Stiff Guide Wire 0.035" J Tip	
Guiding catheter	Guiding Catheter 5 FR 220CM Guiding Catheter 5 FR 320CM Guiding Catheter 6 FR 220CM Guiding Catheter 6 FR 320CM Guiding Catheter 6 FR 45CM Guiding Catheter 7 FR 220CM Guiding Catheter 7 FR 320CM	Ila
Multi Band Ligator	Band ligator Set- SBLS-6-F*, SBLS-6-O*, SBLS-7-F*, SBLS-7-O*-- Suitable For 9.5 To 11.2 Mm Endoscope F= Thread Length 175cm O= Thread Length 155cm With 6 Loaded BANDS With 7 Loaded BANDS Band Ligator Set-- SBLS-6-P-F*, SBLS-6-P-O*--- suitable for 8.0 mm to 9.5 mm endoscope F= Thread Length 175cm O= Thread Length 155cm With 6 Loaded BANDS With 7 Loaded BANDS Barrel SBL-6-F*, SBL-6-O* F = Thread Length 175CM O = thread length 155CM With 6 Loaded BANDS SBL-7-F* & SBL-7-O*	Ila



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	F = Thread Length 175CM O = Thread Length 155CM With 7 Loaded BANDS Barrel SBL-6-P-F* & SBL-6-P-O* F = Thread Length 175CM O = Thread Length 155CM For 8.0 to 9.5mm endoscope with 6 loaded bands Band Ligator Set SBLS-6-C & SBLS-7-C Suitable For 12.8 To 13.5 Mm Endoscope With 6 loaded bands Barrel SBL-6-C & SBL-7-C Suitable For 12.8 To 13.5 Mm Endoscope With 6 Loaded bands With 7 loaded bands	
Esophageal dilator	Esophageal Dilator Diameter from 5 mm to 20 mm, Length 70 cm to 100 cm.	Ila
Esophageal balloon dilator	Esophageal Balloon Dilator 6mm X 4cm balloon Total Length 180cm Esophageal balloon dilator 8mm X 4cm balloon total length 180cm Esophageal balloon dilator 10mm X 4cm balloon total length 180cm Esophageal balloon dilator 12mm X 6cm balloon total length 180cm Esophageal balloon dilator 14mm X 6cm balloon total length 180cm Esophageal balloon dilator 16mm X 8cm balloon total length 180cm Esophageal balloon dilator 18mm X 4cm balloon total length 180cm Achalasia Balloon Dilator 25mm X 80mm balloon total length 90cm Achalasia Balloon Dilator 30mm X 80mm balloon total length 90cm Achalasia Balloon Dilator 35mm X 80mm balloon total length 90cm Achalasia Balloon Dilator Set Balloon Diameter (25mm, 30 Mm, 35mm) With Neg Guide Wire Of 0.035" Having 260cm Length 3 Stage Balloon Dilator Balloon Length 55mm S-3BD-101112, length- 180cm S-3BD-121315, length- 180cm S-3BD-151618, length- 180cm S-3BD-181920, length- 180cm S-3BD-101112C, length- 240cm S-3BD-121315C, length- 240cm S-3BD-151618C, length- 240cm S-3BD-181920C, length- 240cm	Ila
Biopsy forcep	• Biopsy forcep with spike S-BF-WS-17, 170cm long • Biopsy forcep without spike S-BF-17, 170cm long • Biopsy forcep with spike S-BF-WS-21, 210cm long	Ila



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	• Choledocho Basket 15 mm • SMMB-CB	
Wire Guided Stone Extraction Balloon	• WIRE GUIDED STONE EXTRACTION BALLOON 16 mm, 200cm SSEC-7	Ila
Sclerotherapy Needle	• SGN-2319, 19G, 170cm • SGN-2319-C, 19G, 230cm • SGN-2320, 20G, 170cm • SGN-2320-C, 20G, 230cm • SGN-2321, 21G, 170cm • SGN-2321-C, 21G, 230cm • SGN-2321-M, 21G, 170cm, Metal Tip • SGN-2321-C-M, 21G, 230cm, Metal Tip • SGN-2322, 22G, 170cm • SGN-2322-C, 22G, 230cm • SSN-2323, 23G, 170cm • SSN-2323-C, 23G, 230cm • SSN-2323-M, 23G, 170cm, Metal Tip • SSN-2323-C-M, 23G, 230cm, Metal Tip • SSN-2324, 24G, 170cm • SSN-2324-C, 24G, 230cm • SSN-2325, 25G, 170cm • SSN-2325-C, 25G, 230cm • SSN-2324-DBE, 24G, 280cm	Ila

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
SHAILI ENDOSCOPY	PLOT NO. 210 & 213, PADRA JAMBUSAR ROAD, VILLAGE: DABHASA, TAL: PADRA, VADODARA – 391440, GUJARAT, INDIA

EU Representative

Mediprotectsprl / bvba, Avenue de saturnelaan2L A, B-1180 Brussels-Belgium, E-mail:
info@mediprotect.com, WebSite: <http://www.mediprotect.com>

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

