

# 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**



Notified Body No.: 2460

For:  
**DNV GL PRESAFE AS**

**Tone Kolpus**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://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        |
| <b>4.0</b> | <b>Correction typographical error in device classification (in bold)</b> | <b>2019-03-22</b> |

### Products covered by this Certificate:

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

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|                      |   |     |
|----------------------|---|-----|
|                      | <p>Biliary Stent Set C Shape PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR)<br/>         Biliary Stent Set Standard PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR)<br/>         Biliary Stent Set Standard PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR)<br/>         Biliary Stent Set Amsterdam PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR)<br/>         Biliary Stent Set Amsterdam PU (5FR, 7FR, 8.5FR, 10FR, 11.5FR)</p>   |     |
| Biliary Stent Pusher | Stent Pusher (5FR, 7FR, 8.5FR, 10FR, 11.5FR)  | Is  |
| Pancreatic Stent     | <p>Pancreatic Stent C Shape PE (5FR, 7FR, 8.5FR, 10FR, 11.5FR)<br/>         Pancreatic Stent C Shape PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR)<br/>         Pancreatic Stent Single Pigtail PE (5FR, 7FR, 8.5FR, 10FR, 11.5FR)<br/>         Pancreatic Stent Straight PTFE (5FR, 7FR, 8.5FR, 10FR, 11.5FR)</p>   | IIb |
| Pancreatic Stent Set | <p>Pancreatic Stent Set For Stent C Shape PE 5FR 5FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PE 7FR 7FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PE 8.5FR 5FR Guiding Catheter,8.5FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PE 10FR 6FR Guiding Catheter,10FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PE 11.5FR 7FR Guiding Catheter, 11.5FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PTFE 5FR 5FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PTFE 7FR, 7FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PTFE 8.5FR, 5FR Guiding Catheter,8.5FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PTFE 10FR 6FR Guiding Catheter,10FR Pusher<br/>         Pancreatic Stent Set For Stent C Shape PTFE 11.5FR, 7FR Guiding Catheter, 11.5FR Pusher<br/>         Pancreatic Stent Set For Stent Straight PTFE 5FR, 5FR pusher<br/>         Pancreatic Stent Set For Stent Straight PTFE 7FR, 7FR Pusher<br/>         Pancreatic Stent Set For Stent Straight PTFE 8.5FR, 5FR Guiding Catheter,8.5FR Pusher<br/>         Pancreatic Stent Set For Stent Straight PTFE 10FR, 6FR Guiding Catheter,10FR Pusher<br/>         Pancreatic Stent Set For Stent Straight PTFE 11.5FR, 7FR Guiding Catheter,11.5FR Pusher<br/>         Pancreatic Stent Set For Stent Single Pigtail PE 5FR 5FR pusher<br/>         Pancreatic Stent Set For Stent Single Pigtail PE 7FR 7FR Pusher<br/>         Pancreatic Stent Set For Stent Single Pigtail PE 8.5FR, 5FR Guiding Catheter,8.5FR Pusher<br/>         Pancreatic Stent Set For Stent Single Pigtail PE 10FR, 6FR Guiding Catheter,10FR Pusher<br/>         Pancreatic Stent Set For Stent Single Pigtail PE 11.5FR, 7FR Guiding Catheter,11.5FR Pusher<br/>         Pancreatic Stent Set For Stent Single Pigtail PTFE 5FR, 5FR pusher<br/>         Pancreatic Stent Set For Stent Single Pigtail PTFE 7FR, 7FR Pusher<br/>         Pancreatic Stent Set For Stent Single Pigtail PTFE 8.5FR, 5FR Guiding</p> | IIb |

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|                  |   |            |
|------------------|---|------------|
|                  | <p>Catheter,8.5FR Pusher<br/>Pancreatic Stent Set For Stent Single Pigtail PTFE 10FR, 6FR Guiding<br/>Catheter,10FR Pusher<br/>Pancreatic Stent Set For Stent Single Pigtail PTFE 11.5FR, 7FR<br/>Guiding Catheter,11.5FR Pusher</p>  |            |
| <p>Guidewire</p> | <p>NEG Guide Wire<br/>Neg Guide Wire 0.032 Straight<br/>Neg Guide Wire 0.032 Angulated<br/>Neg Guide Wire 0.032 J Tip<br/>Neg Guide Wire 0.035 Straight<br/>Neg Guide Wire 0.035 Angulated<br/>Neg Guide Wire 0.035 J Tip<br/>Neg Guide Wire 0.038 Straight<br/>Neg Guide Wire 0.038 Angulated<br/>Neg Guide Wire 0.038 J Tip<br/>Neg Guide Wire 0.025 Straight<br/>Neg Guide Wire 0.025 Angulated<br/>Neg Guide Wire 0.025 J Tip</p> <p>Neg Guide Wire 0.032 Straight For Double Balloon Endoscope<br/>Neg Guide Wire 0.032 Angulatedfor Double Balloon Endoscope<br/>Neg Guide Wire 0.032 J Tip For Double Balloon Endoscope<br/>Neg Guide Wire 0.035 Straight For Double Balloon Endoscope<br/>Neg Guide Wire 0.035 Angulatedfor Double Balloon Endoscope<br/>Neg Guide Wire 0.035 J Tip For Double Balloon Endoscope</p> <p>Hydra Neg Wire 0.025 Straight<br/>Hydra Neg Wire 0.025 Angulated<br/>Hydra Neg Wire 0.025 J Tip<br/>Hydra Neg Wire 0.032 Straight<br/>Hydra Neg Wire 0.032 Angulated<br/>Hydra Neg Wire 0.032 J Tip</p> <p>Hydra Neg Wire 0.035 Straight<br/>Hydra Neg Wire 0.035 Angulated<br/>Hydra Neg Wire 0.035 J Tip<br/>Hydra Neg Wire 0.038 Straight<br/>Hydra Neg Wire 0.038 Angulated<br/>Hydra Neg Wire 0.038 J Tip</p> <p>Hydra Neg Combo Guide (Hycg)Wire 0.032 Straight<br/>Hydra Neg Combo Guide (Hycg) Wire 0.035 Straight</p> <p>Super Stiff Hydra Neg Wire(Sshy neg) 0.025 Straight<br/>Super stiff hydra neg wire (sshy neg) 0.025 angulated<br/>Super Stiff Hydra Neg Wire(Sshy neg) 0.025 J Tip<br/>Super stiff hydra neg wire (sshy neg) 0.032 straight<br/>Super Stiff Hydra Neg Wire(Sshy neg) 0.032 Angulated<br/>Super Stiff Hydra Neg Wire (Sshy neg)0.032 J Tip<br/>Super Stiff Hydra Neg Wire(Sshy neg) 0.035 Straight</p> | <p>Ila</p> |

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

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|                            | <p>F = Thread Length 175CM<br/>O = Thread Length 155CM<br/>With 7 Loaded BANDS</p> <p>Barrel SBL-6-P-F* &amp; SBL-6-P-O*<br/>F = Thread Length 175CM<br/>O = Thread Length 155CM<br/>For 8.0 to 9.5mm endoscope with 6 loaded bands</p> <p>Band Ligator Set<br/>SBLS-6-C &amp; SBLS-7-C<br/>Suitable For 12.8 To 13.5 Mm Endoscope<br/>With 6 loaded bands</p> <p>Barrel SBL-6-C &amp; SBL-7-C<br/>Suitable For 12.8 To 13.5 Mm Endoscope<br/>With 6 Loaded bands<br/>With 7 loaded bands</p>   |     |
| Esophageal dilator         | Esophageal Dilator Diameter from 5 mm to 20 mm, Length 70 cm to 100 cm.   | Ila |
| Esophageal balloon dilator | <p>Esophageal Balloon Dilator 6mm X 4cm balloon Total Length 180cm<br/>Esophageal balloon dilator 8mm X 4cm balloon total length 180cm<br/>Esophageal balloon dilator 10mm X 4cm balloon total length 180cm<br/>Esophageal balloon dilator 12mm X 6cm balloon total length 180cm<br/>Esophageal balloon dilator 14mm X 6cm balloon total length 180cm<br/>Esophageal balloon dilator 16mm X 8cm balloon total length 180cm<br/>Esophageal balloon dilator 18mm X 4cm balloon total length 180cm</p> <p>Achalasia Balloon Dilator 25mm X 80mm balloon total length 90cm<br/>Achalasia Balloon Dilator 30mm X 80mm balloon total length 90cm<br/>Achalasia Balloon Dilator 35mm X 80mm balloon total length 90cm</p> <p>Achalasia Balloon Dilator Set Balloon Diameter (25mm, 30 Mm, 35mm)<br/>With Neg Guide Wire Of 0.035" Having 260cm Length</p> <p>3 Stage Balloon Dilator Balloon Length 55mm<br/>S-3BD-101112, length- 180cm<br/>S-3BD-121315, length- 180cm<br/>S-3BD-151618, length- 180cm<br/>S-3BD-181920, length- 180cm<br/>S-3BD-101112C, length- 240cm<br/>S-3BD-121315C, length- 240cm<br/>S-3BD-151618C, length- 240cm<br/>S-3BD-181920C, length- 240cm</p> | Ila |
| Biopsy forcep              | <ul style="list-style-type: none"> <li>• Biopsy forcep with spike<br/>S-BF-WS-17, 170cm long</li> <li>• Biopsy forcep without spike<br/>S-BF-17, 170cm long</li> <li>• Biopsy forcep with spike<br/>S-BF-WS-21, 210cm long</li> </ul>   | Ila |

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|---------------------------------------|--|-----|
| Hot biopsy forcep (active device)     | <ul style="list-style-type: none"> <li>Biopsy forcep without spike S-BF-21, 210cm long</li> <li>Hot biopsy forcep S-BF-H-17, 170cm long</li> <li>Hot biopsy forcep, S-BF-H-21, 210cm long</li> </ul>   | IIb |
| Cystostome (active device)            | <ul style="list-style-type: none"> <li>Cystostome 6fr S-CYS-6, length-180cm</li> <li>Cystostome 8fr S-CYS-8, length-180cm</li> <li>Cystostome 10fr S-CYS-10, length-180cm</li> <li>Cystostome 7fr S-CYS-7, length-180cm</li> </ul>   | IIb |
| Endoscissor (active device)           | <ul style="list-style-type: none"> <li>Hot scissor-160cm S-ES-160-H, length-160cm</li> <li>Hot scissor-230cm S-ES-230-H, length-230cm</li> <li>Endo scissor-160cm, rotatable and hot S-ES-160-R-H, length-160cm</li> <li>Endo scissor-230cm, rotatable and hot S-ES-230-R-H, length-230cm</li> </ul>   | IIb |
| Needle knife (active device)          | <ul style="list-style-type: none"> <li>Needle knife SNK-100, total length 200cm and needle length 5mm</li> <li>Needle knife - double balloon enteroscope SNK-100-DBE, total length 280cm and needle length 5mm</li> <li>Wire guided needle knife SNK-100-WG, total length 200cm and needle length 5mm</li> <li>Needle knife - double balloon enteroscope SNK-100-WG-DBE, total length 280cm and needle length 5mm</li> </ul> | IIb |
| Ball tip knife (active device)        | <ul style="list-style-type: none"> <li>Ball tip knife SNK-IP, total length 180cm and knife length 7mm</li> </ul>   | IIb |
| Hook knife (active device)            | <ul style="list-style-type: none"> <li>Hook knife SNK-X, total length 180cm and knife length 7mm</li> </ul>  | IIb |
| Hook knife with flush (active device) | <ul style="list-style-type: none"> <li>Hook knife with flush SNK-X-F, total length 180cm and knife length 7mm</li> </ul>   | IIb |
| Flexi knife (active device)           | <ul style="list-style-type: none"> <li>Flexi knife SNK-XP, total length 180cm and knife length 7mm</li> </ul>  | IIb |
| Polypectomy snare                     | <ul style="list-style-type: none"> <li>Polypectomy snare oval SPSO-LOOP x diameter, oval shape</li> </ul>  | IIb |

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| <p>(active device)</p>                    | <ul style="list-style-type: none"> <li>• Polypectomy snare hexagonal<br/>SPSH-LOOP x diameter, hexagonal shape</li> <li>• Polypectomy snare crecent<br/>SPSC-LOOP x diameter, crecent shape</li> <li>• Polypectomy snare oval double balloon endroscope<br/>SPSO-30-DBE, oval shape</li> <li>• Polypectomy snare duckbill loop diameter 25mm<br/>SPSD-25, duckbill shape</li> <li>• Polypectomy snare monofilament<br/>SPSM-LOOP x diameter, made of monofilament</li> <li>• Polypectomy snare oval rotatable<br/>SPSO-LOOP x diameter-r, oval shape</li> <li>• Polypectomy snare hexagonal rotatable<br/>SPSH-LOOP x diameter-r, hexagonal shape</li> <li>• Polypectomy snare crecent rotatable<br/>SPSC-LOOP x diameter-r, crecent shape</li> <li>• Polypectomy snare monofilament rotatable<br/>SPSM-LOOP x diameter-r, made of monofilament</li> </ul>   |            |
| <p>Sphincterotome<br/>(active device)</p> | <ul style="list-style-type: none"> <li>• Sphincterotome short nose (sn) with insulation –<br/>SSPH-SN-20 - tip length 5.0 mm, Total loop 20mm, insulation wire length = 4mm</li> <li>• Sphincterotome short nose(sn) with insulation –<br/>SSPH-SN-25 - tip length 5.0 mm, Total loop 25mm, insulation wire length = 8 mm</li> <li>• Sphincterotome short nose (sn) with insulation –<br/>SSPH-SN-30 - tip length 5.0 mm, Total loop 30mm insulation wire length = 10 mm</li> <li>• Sphincterotome long nose (ln)with insulation<br/>SSPH-LN-20 - tip length 8 mm, total loop 20mm insulation wire length = 4mm</li> <li>• Sphincterotome long nose(ln) with insulation<br/>SSPH-LN-25 - tip length 8 mm, total loop 25mm insulation wire length = 8 mm</li> <li>• Sphincterotome long nose(ln) with insulation<br/>SSPH-LN-30 - tip length 8 mm, total loop 30mm insulation wire length = 10 mm</li> <li>• Sphincterotome no nose (nn) non insulated(ni)<br/>SSPH-NN-NI-20 - tip length 0 mm, total loop 20mm</li> <li>• Sphincterotome no nose (nn) non insulated(ni)<br/>SSPH-NN-NI-25 - tip length 0 mm, total loop 25mm</li> <li>• Sphincterotome no nose (nn), non insulated(ni)<br/>SSPH-NN-NI-30 - tip length 0 mm, total loop 30mm</li> <li>• Sphincterotome no nose (nn) with insulation<br/>SSPH-NN-20 - tip length 0 mm, total loop 20mm insulation wire length = 4mm</li> <li>• Sphincterotome no nose (nn)with insulation<br/>SSPH-NN-25 - tip length 0 mm, total loop 25mm insulation wire length = 8 mm</li> <li>• Sphincterotome no nose (nn)with insulation<br/>SSPH-NN-30 - tip length 0 mm, total loop 30mm insulation wire</li> </ul> | <p>IIb</p> |



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|                            | <p>length = 10 mm</p> <ul style="list-style-type: none"> <li>• Sphincterotome reverse cut (rc) non insulated (ni)<br/>SSPH-RC-NI-20 - reverse cutting shape, tip length 2.0mm, total loop 20mm</li> <li>• Sphincterotome reverse cut (rc) non insulated(ni)<br/>SSPH-RC-NI-25 - reverse cutting shape, tip length 2.0mm, total loop 25mm</li> <li>• Sphincterotome reverse cut (rc) non insulated(ni)<br/>SSPH-RC-NI-30 - reverse cutting shape, Tip length 2.0mm, total loop 30mm</li> <li>• Sphincterotome short nose (sn) non insulated(ni)<br/>SSPH-SN-NI-20 - tip length 5.0mm, total loop 20mm</li> <li>• Sphincterotome short nose(sn) non insulated(ni)<br/>SSPH-SN-NI-25 - tip length 5.0mm, total loop 25mm</li> <li>• Sphincterotome short nose (sn) non insulated(ni)<br/>SSPH-SN-NI-30 - tip length 5.0mm, total loop 30mm</li> <li>• Sphincterotome long nose (ln) non insulated(ni)<br/>SSPH-LN-NI-20 - tip length 8 mm, total loop 20mm</li> <li>• Sphincterotome long nose (ln) non insulated(ni)<br/>SSPH-LN-NI-25 - tip length 8 mm, total loop 25mm</li> <li>• Sphincterotome long nose (ln) non insulated(ni)<br/>SSPH-LN-NI-30 - tip length 8 mm, total loop 30mm</li> <li>• Sphincterotome short nose (sn)with insulation fordoube balloon enteroscope<br/>SSPH-SN-20-DBE - tip length 5.0 mm, Total loop 20mm, total length - 280cm</li> <li>• Sphincterotome short nose(sn) with insulation For double balloon enteroscope<br/>SSPH-SN-25-DBE - tip length 5.0 mm, Total loop 25mm, total length - 280cm</li> <li>• Sphincterotome short nose (sn) with insulationFor double balloon enteroscope<br/>SSPH-SN-30-DBE - tip length 5.0 mm, Total loop 30mm, total length - 280cm</li> <li>• Sphincterotome long nose (ln) with insulationFor double balloon enteroscope<br/>SSPH-LN-20-DBE - tip length 8 mm, total loop 20mm, total Length - 280cm</li> <li>• Sphincterotome long nose (ln) with insulationFor double balloon enteroscope<br/>SSPH-LN-25-DBE - tip length 8 mm, total loop 25mm, total Length - 280cm</li> <li>• Sphincterotome long nose (ln) with insulation For double balloon enteroscope<br/>SSPH-LN-30-DBE - tip length 8 mm, total loop 30mm, total length - 280cm</li> </ul> |            |
| <p>Biliary Metal Stent</p> | <ul style="list-style-type: none"> <li>• Biliary metal stent 6cm<br/>S-MBS-6, length 6cm</li> <li>• Biliary metal stent 8cm<br/>S-MBS-8, length 8cm</li> </ul>   | <p>IIb</p> |

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|                         | <ul style="list-style-type: none"> <li>Biliary metal stent 10cm<br/>S-MBS-10, length 10cm</li> <li>Biliary metal stent 12cm<br/>S-MBS-12, length 12cm</li> </ul>  |     |
| Esophageal Metal Stent  | <ul style="list-style-type: none"> <li>Esophageal metal stent 10cm<br/>S-ES-10, total length 10cm</li> <li>Esophageal metal stent 12cm<br/>S-ES-12, total length 12 cm</li> <li>Esophageal metal stent 15cm<br/>S-ES-15, total length 15cm</li> </ul>   | IIb |
| Biliary Balloon Dilator | <ul style="list-style-type: none"> <li>Biliary balloon dilator 6mm total length 200cm<br/>S-BBD-640, balloon diameter 6mm, Length 4.0cm</li> <li>Biliary balloon dilator 8mm total length 200cm<br/>S-BBD-840, balloon diameter 8mm, Length 4.0cm</li> <li>Biliary balloon dilator 10mm total length 200cm<br/>S-BBD-1040, balloon diameter 10mm, Length 4.0cm</li> </ul>   | IIa |
| Biliary Dilator         | <ul style="list-style-type: none"> <li>Biliary dilator 7fr<br/>S-BD-7, radioopaque ptfе diameter 7fr, length 200cm</li> <li>Biliary dilator 8.5 fr<br/>S-BD-8.5, radioopaque ptfе diameter 8.5fr, length 200cm</li> <li>Biliary dilator 10fr<br/>S-BD-10, radioopaque ptfе diameter 10fr, length 200cm</li> <li>Biliary dilator 11.5 fr<br/>S-BD-11.5, radioopaque ptfе diameter 11.5fr, length 200cm</li> <li>Biliary dilator 5 fr<br/>S-BD-5, radioopaque ptfе diameter 5fr, length 200cm</li> <li>Biliary dilator 6 fr<br/>S-BD-6, radioopaque ptfе Diameter 6fr, length 200cm</li> <li>Biliary dilator 9 fr<br/>S-BD-9, radioopaque ptfе diameter 9fr, length 200cm</li> <li>Biliary dilator 7fr For double balloon enteroscope<br/>S-BD-7-DBE, radioopaque ptfе diameter 7fr length - 280cm</li> <li>Biliary dilator 8.5fr For double balloon Enteroscope<br/>S-BD-8.5-DBE, radioopaque, PTFE diameter 8.5fr length - 280cm</li> <li>Biliary dilator 10fr For double balloon Enteroscope<br/>S-BD-10-DBE, radioopaque PTFE diameter 10fr length - 280cm</li> <li>Biliary dilator 11.5fr For double balloon Enteroscope<br/>S-BD-11.5-DBE, radioopaque PTFE diameter 11.5fr length - 280cm</li> <li>Biliary dilator 5fr For double balloon Enteroscope<br/>S-BD-5-DBE, radioopaque PTFE diameter 5fr length - 280cm</li> <li>Biliary dilator 6fr For double balloon Enteroscope<br/>S-BD-6-DBE, radioopaque PTFE dDiameter 6fr length - 280cm</li> <li>Biliary dilator 9fr For double balloon Enteroscope<br/>S-BD-9-DBE, radioopaque PTFE Diameter 9fr length - 280cm</li> </ul> | IIa |
| Cytology Brush          | <ul style="list-style-type: none"> <li>Wire guided cytology brush<br/>S-CY-DL, double lumen</li> <li>Cytology brush<br/>S-CY170, length 170cm</li> </ul>  | IIa |

# EC Certificate

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Project No.:  
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Valid Until:  
**08 June 2023**

|                                  |   |     |
|----------------------------------|---|-----|
|                                  | <ul style="list-style-type: none"> <li>• Cytology brush<br/>S-CY230, length 230cm</li> <li>• Cytology brush<br/>S-CY-S, length 325cm</li> </ul>   |     |
| ERCP Cannula                     | <ul style="list-style-type: none"> <li>• ERCP cannula tapered tip<br/>S-ERC-T-SL, tip 4.5fr, working length-200cm</li> <li>• ERCP cannula ball tip<br/>S-ERC-B-SL, tip 5.5fr, ball tip, working length-200cm</li> <li>• Wire guided ERCP cannula tapered tip<br/>S-ERC-T-DL, tip 5.5fr, double lumen, working length-200cm</li> <li>• ERCP cannula tapered tip For double balloon Enteroscope<br/>S-ERC-T-DL-DBE, tip 5.5fr length - 280cm</li> <li>• ERCP cannula ball tip For double balloon Enteroscope<br/>S-ERC-B-SL-DBE, tip 5.5fr, ball tip length - 280cm</li> <li>• Wire guided ERCP cannula tapered tip For double balloon Enteroscope<br/>S-ERC-T-SL-DBE, tip 4.5 fr, double lumen length - 280cm</li> </ul> | IIa |
| PEG Kit and PEG Replacement Tube | <ul style="list-style-type: none"> <li>• PEG KIT 20 Fr<br/>S-PEG-20</li> <li>• PEG KIT WITH SNARE 20 Fr<br/>S-PEG-20-SN</li> <li>• PEG KIT 22 Fr<br/>S-PEG-22</li> <li>• PEG KIT WITH SNARE 22 Fr<br/>S-PEG-22-SN</li> <li>• PEG KIT 24 Fr<br/>S-PEG-24</li> <li>• PEG KIT WITH SNARE 24 Fr<br/>S-PEG-24-SN</li> <li>• REPLACEMENT PEG TUBE 20 Fr<br/>S-GRT-20</li> <li>• REPLACEMENT PEG TUBE 22 Fr<br/>S-GRT-22</li> <li>• REPLACEMENT PEG TUBE 24 Fr<br/>S-GRT-24</li> </ul>   | IIb |
| Basket                           | <ul style="list-style-type: none"> <li>• Retrievl Basket</li> <li>• Wire Guided Retrieval Basket 15, 20, 25, 30, 35, 40, 45, 50 mm</li> <li>• Tip Guided Retrieval Basket 15, 20, 25, 30, 35, 40, 45, 50 mm</li> <li>• MEMORY BASKET 15, 20, 25, 30, 35, 40, 45 mm</li> <li>• MEMORY BASKET TIP LESS 15, 20, 25, 30, 35, 40, 45 mm</li> <li>• WIRE GUIDED MEMORY BASKET 30, 35, 40 mm</li> <li>• LITHO- BASKET TTS 25, 30, 35, 40, 45, 50, 55 mm</li> <li>• Pancreatic Basket 15 mm</li> <li>• SMMB-P</li> </ul>  | IIa |

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|                                      |  |            |
|--------------------------------------|--|------------|
|                                      | <ul style="list-style-type: none"> <li>• Choledocho Basket 15 mm</li> <li>• SMMB-CB</li> </ul>   |            |
| Wire Guided Stone Extraction Balloon | <ul style="list-style-type: none"> <li>• WIRE GUIDED STONE EXTRACTION BALLOON 16 mm, 200cm SSEC-7</li> </ul>   | <b>Ila</b> |
| Sclerotherapy Needle                 | <ul style="list-style-type: none"> <li>• SGN-2319, 19G, 170cm</li> <li>• SGN-2319-C, 19G, 230cm</li> <li>• SGN-2320, 20G, 170cm</li> <li>• SGN-2320-C, 20G, 230cm</li> <li>• SGN-2321, 21G, 170cm</li> <li>• SGN-2321-C, 21G, 230cm</li> <li>• SGN-2321-M, 21G, 170cm, Metal Tip</li> <li>• SGN-2321-C-M, 21G, 230cm, Metal Tip</li> <li>• SGN-2322, 22G, 170cm</li> <li>• SGN-2322-C, 22G, 230cm</li> <li>• SSN-2323, 23G, 170cm</li> <li>• SSN-2323-C, 23G, 230cm</li> <li>• SSN-2323-M, 23G, 170cm, Metal Tip</li> <li>• SSN-2323-C-M, 23G, 230cm, Metal Tip</li> <li>• SSN-2324, 24G, 170cm</li> <li>• SSN-2324-C, 24G, 230cm</li> <li>• SSN-2325, 25G, 170cm</li> <li>• SSN-2325-C, 25G, 230cm</li> <li>• SSN-2324-DBE, 24G, 280cm</li> </ul> | <b>Ila</b> |

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,<br>VILLAGE: DABHASA, TAL: PADRA, VADODARA – 391440,<br>GUJARAT, INDIA |

### EU Representative

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

# EC Certificate

## Full Quality Assurance System

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

Valid Until:  
**08 June 2023**

### 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



# Management System Certificate

|                                   |                             |              |
|-----------------------------------|-----------------------------|--------------|
| Certificate No.:                  | Initial Certification Date: | Valid Until  |
| 251747-2017-AQ-IND-NA-PS Rev. 2.0 | 8 March 2018                | 7 March 2024 |

This is to certify that the quality system of:

## SHAILI ENDOSCOPY

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

has been found to conform to the Quality Management System standard:

### ISO 13485:2016/NS-EN ISO 13485:2016

This certificate is valid for the following scope:

**Design, Manufacture and supply of Urology, Bronchoscopy, Gastroenterology and Gynecology Medical Devices**

Place and date:  
Høvik, 4 March 2021

Check Validity



For the Issuing office:  
DNV Product Assurance AS

*Eugenie Winger Husebye*  
Eugenie Winger Husebye  
Technical Reviewer

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

Accredited Body: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-11-IBO13485-11,

rev.0