



Management System Certificate

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|-----------------------------------|-----------------------------|--------------|
| 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

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

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

rev.0

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 Web Site: www.shailiendoscopy.com |
| Product Type | : Naso Jejunal Feeding Tube |
| Product Model | : As Per Annexure A. |
| Product Intended Use | : Naso jejunal feeding tubes are frequently used for long-term enteral Nutrition. |
| Product Classification | : Naso Jejunal Feeding Tube 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 9 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 Naso Jejunal Feeding Tube 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; ISO 11135:2014/A1:2019 ;EN 62366:2015; EN ISO 11138-2:2009; EN ISO 11607-1:2009/ISO 11607-1:2019, EN ISO 11607-2:2006/ISO 11607-2:2019, EN ISO 11737-1:2006/ISO 11737-1:2018; EN ISO 11737-2:2009/ ISO 11737-2:2018/ISO 11737-2:2020 ; 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/JFT Rev.03 dt. 01/01/2022

Annexure A-Product Models

| Reference No. | Product Name | Size | Length | GMDN Code | CE Classification |
|---------------|---------------------------|------|--------|-----------|-------------------|
| S-NJFT-10120 | NASO JEJUNAL FEEDING TUBE | 10FR | 120CM | 38564 | IIb |
| S-NJFT-10155 | NASO JEJUNAL FEEDING TUBE | 10FR | 155CM | 38564 | IIb |
| S-NJFT-12120 | NASO JEJUNAL FEEDING TUBE | 12FR | 120CM | 38564 | IIb |
| S-NJFT-12155 | NASO JEJUNAL FEEDING TUBE | 12FR | 155CM | 38564 | IIb |
| S-NJFT-14120 | NASO JEJUNAL FEEDING TUBE | 14FR | 120CM | 38564 | IIb |
| S-NJFT-14155 | NASO JEJUNAL FEEDING TUBE | 14FR | 155CM | 38564 | IIb |
| S-NJFT-16120 | NASO JEJUNAL FEEDING TUBE | 16FR | 120CM | 38564 | IIb |
| S-NJFT-16155 | NASO JEJUNAL FEEDING TUBE | 16FR | 155CM | 38564 | IIb |

AMENDMENT HISTORY

| Revision No. | Revision Date | Revision Done | Revised By |
|--------------|---------------|--|------------|
| 00 | 10/07/2017 | Initial Version of Declaration of Conformity | QA |
| 01 | 01/07/2020 | Applied standards updated in DOC | QA |
| 02 | 21/07/2021 | Applied standards updated in DOC | QA |
| 03 | 01/01/2022 | Remove EU Representatives | QA |

Doc. No.: SE/DOC/JFT Rev.03 dt. 01/01/2022

