

# Certificate

acc. to **ISO 13485:2016**

**Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes**

**Certificate Registration No.: 20-1604-M**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure. **Brazil:** RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009. **Canada:** Medical Devices Regulations – Part 1- SOR/98-282. **USA:** United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

**Intelligent Endoscopy, LLC**  
**4740 Commercial Park Court, Suite 1**  
**Clemmons, NC 27012, USA**

Facility ID: **F004282**

Additional sites covered by QM System: **N/A**

List of Products: **See Annex 1**

**Scope:**

**Design, Manufacturing, and Distribution of Endoscopic Banding  
Devices for Variceal and Hemorrhoidal Ligation, and Endoscopic  
Mucosal Resection**

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

**TUV USA, Inc. (a Member of the TÜV NORD Group)**

**215 Main Street, Suite 1, Salem, NH 03079, USA**

**Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: [medical-usa@tuv-nord.com](mailto:medical-usa@tuv-nord.com)**

*TUV USA, Inc. is an MDSAP Recognised Auditing Organization*



Audit Report Reference No.: **22-4016 RC**

Initial Certification Date: **2020-02-22**

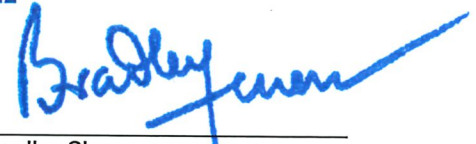
Current Cycle Start Date: **2023-02-22**

Effective Date:

**2023-02-22 / ed. 4**

Valid Until:

**2026-02-21**



Bradley Chen  
Vice President – Medical, Americas  
Medical Products Division  
TUV USA, Inc.

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Company Name: Intelligent Endoscopy, LLC  
Central (HQ) Office Address: 4740 Commercial Park Court, Suite 1  
Clemmons, NC 27012, USA



Products	UMDNS	GMDN
SLK-6	12-335	46680
SLP-6	12-335	46680
SLK-6-LF	12-335	46680
SLP-6-LF	12-335	46680
SB-EMR-K	N/A	61613
SB-EMR-K-12	N/A	61613
SB-EMR-K-9.4	N/A	61613
SB-EMR-P	N/A	61613
SB-EMR-P-12	N/A	61613
SB-EMR-P-9.4	N/A	61613
SS-230-1	N/A	61613

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