

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:

Brazil: RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; 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

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **19-3688 RC-SA1-SA3**

Certificate Initial Issue Date: **2020-02-22**

Current Cycle Start Date: **2020-02-22**

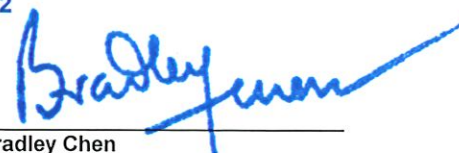
Certificate Revised Date: **2021-06-22**

Effective Date:

2021-06-22 / ed. 2

Valid Until:

2023-02-21



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

Certificate Registration No. : 20-1604-M / ed. 2
Company Name: Intelligent Endoscopy, LLC
Central 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-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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