TÜV NORD

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

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

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Endoscopic banding device for variceal and hemorrhoidal ligation

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 44 232 142007
Bericht Nr. / *Report No.* 3525 2996

Gültigkeit / *Validity*
von / *from* 2019-11-18
bis / *until* 2023-02-10
Edition 4

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-11-18

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 44 232 142007

Produkte der Klasse IIa *Products of class IIa*	Typ *Type*	UMDNS GMDN
SmartBand Multi-Band Ligation Devices Latex	SmartBand Multi-Band Ligation Pack SmartBand Multi-Band Ligation Kit	12-335 12-335
SmartBand SafeGrip Multi-Band Ligation Devices Latex free	SmartBand SafeGrip Multi-Band Ligation Pack SmartBand SafeGrip Multi-Band Ligation Kit	12-335 12-335
SmartBand EMR Product Family	SmartBand EMR Kit SmartBand EMR Pack SmartSnare EMR Hexagonal Snare	61613 61613 61613

Bericht Nr. / *Report No.* 3528 0613

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 5

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

TÜVNORD

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

Intelligent Endoscopy, LLC
4740 Commercial Park Court, Suite 1
Clemmons, North Carolina
27012 USA

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Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

medical@tuev-nord.de
tuev-nord-cert.com/en

TÜV®

Reference	Contact	Direct Dial	Date
No.: 8003067514	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	23 April 2024

Notified Body Confirmation Letter
Reference: 8003067514

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, TÜV Nord Cert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Intelligent Endoscopy, LLC
4740 Commercial Park Court, Suite 1
Clemmons, North Carolina
27012 USA
US-MF-000022828

TÜVNORD

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

TÜVNORD i. V. Digital unterschrieben von Mühlenberg Kevin Datum: 2024.05.02 07:48:59 +02'00'

i. V. Kevin Mühlenberg
Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. V. Digital unterschrieben von Hoy Benjamin Datum: 2024.05.02 09:52:05 +02'00'

i. V. Benjamin Hoy
Head of TIC Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SmartBand EMR Kit SB-EMR-K SB-EMR-K-12 SB-EMR-K-9.4	IIb	N/A	Certificate #44232142007, NB #0044
SmartBand EMR Pack SB-EMR-P SB-EMR-P-12 SB-EMR-P-9.4	IIb	N/A	Certificate #44232142007, NB #0044
SmartBand Multi-Band Ligation Devices Latex SLK-6 SLP-6	IIa	N/A	Certificate #44232142007, NB #0044
SmartBand SafeGrip Multi-Band Ligation Devices Latex Free SLK-6-LF SLP-6-LF	IIa	N/A	Certificate #44232142007, NB #0044
SmartSnare EMR Hexagonal Snare SS-230-1	IIb	N/A	Certificate #44232142007, NB #0044

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
1/31/2024	8003067514	Initial issue - on basis of P111F007 R04 (2023.08) - Product List_IE Oct 2023
4/23/2024	8003067514	Update of signee