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 Kennnummer 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
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ZLG-BS-236.10.16

Intelligent Endoscopy

4740 Commercial Park Court
Suite 1
Clemmons, NC 27012
Primary email: melissa_haller@steris.com

Memo

To: Whom it may concern

From: Melissa Haller, President MH 14 Sept 2023

CC: N/A

Date: 14 September 2023

Re: EU MDR 2017/745 Extension

This memo supports Regulation (EU) 2023/607 that amends MDR Articles 120(2), (3), and (4) and MDR Articles 122 and 123. Devices covered by expired MDD certificates that are eligible for the aforementioned Regulation are those that meet one of the following conditions:

1. At the moment of the expiry, the manufacturer has signed a contract with a Notified Body for the conformity assessment of the device in question;
2. Alternatively, a national competent authority may have granted a derogation in accordance with MDR Article 59;
3. Or have required the manufacturer to carry out the conformity assessment procedure within a specific time period in accordance with MDR Article 97.[1]

Intelligent Endoscopy qualifies under this amendment via option 1. Whereas, IE received an Interim Declaration from TUV Nord related to the *"Certification of a Quality Management System according to (EU) 2017/745 (MDR).* The official MDR application was dated 05 August 2022.

As it relates to Article 120, paragraph 3c, Intelligent Endoscopy affirms the following:

1. The Quality Management System continues to comply with 93/42/EEC. There have been significant changes to the Quality Management System since our last Notified Body audit.
2. There are no significant changes in the design and intended purpose of the marketed medical devices.
3. The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
4. Intelligent Endoscopy's MDR application was accepted by TUV Nord and completion of the MDR process is expected in Q3 2023.

Enclosed: Interim Declaration

TÜV NORD Certification

TÜV NORD CERT GmbH • P.O. Box 10 32 61 • 45032 Essen • Germany

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TÜV®

Our / Your Reference	Contact	Direct Dial	Date
44232142007 / 22-3994 CA	E-Mail: ibonanno@tuv-nord.com	Phone: 603-870-8023 Opt. 1	20.01.2023

Interim declaration

Certification of a Quality Management System according to (EU) 2017/745 (MDR)

TÜV NORD CERT GmbH as a notified body for medical devices under the Medical device regulation (EU)2017/745 herewith confirms that company Intelligent Endoscopy holds a valid certificate for the conformity assessment according to the medical device directive 93/42/EEC, certificate number: 44 232 142007, valid until 2023-02-10.

The company is subject to continued mandatory surveillance activities by TÜV NORD CERT GmbH until the expiry of the certificate.

TÜV NORD CERT GmbH received the signed official application for a conformity procedure under (EU) 2017/745 (MDR) dated 05.08.2022. The application is currently under review.

Due to the complexity of the conformity assessment procedure and the unforeseeable final decision concerning the certification neither the issuance itself nor the exact date of issuance of the certificate under the MDR can be predicted at this point.

TÜV NORD i.V. Digital unterschrieben von Frankewitz Tanja Datum: 2023.01.20 14:48:02 +01'00'

Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH

Ivy Bonanno Digitally signed by Ivy Bonanno Date: 2023.01.20 08:28:26 -05'00'

Project Management