Intelligent Endoscopy

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

Manufacturer:	Intelligent Endoscopy, LLC
Address:	4740 Commercial Park Court Suite 1 Clemmons, NC, 27012 United States
EC Representative:	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands

We, the manufacturer, declare under our sole responsibility that

	Product Name :	SmartBand Multi-Band Ligation Pack SmartBand Multi-Band Ligation Kit SmartBand SafeGrip Multi-Band Ligation Kit SmartBand SafeGrip Multi-Band Ligation Pack SmartBand EMR Kit SmartBand EMR Pack SmartSnare EMR Hexagonal Snare	
the medical device(s)	Type/model, identification of product allowing traceability (Where applicable) :	SLP-6 SLK-6 SLP-6-LF SLK-6-LF SB-EMR-K SB-EMR-K-12 SB-EMR-9.4 SB-EMR-P SB-EMR-P-12 SB-EMR-P-9.4 SS-230-1 **All lot numbers**	Ref: IE11001 Ref: IE11002 Ref: IE11003 Ref: IE11004 Ref: IE11007 Ref: IE11011 Ref: IE11020 Ref: IE11008 Ref: IE11012 Ref: IE11021 Ref: IE11013
of class	according to annex IX of directive 93/42/EEC :	IIa, Rule 5 IIa Rule 9	

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents	All applicable standards have been applied.
Conformity assessment procedure	MDD 93/42/EEC Annex II.3 (without 4)
Notified Body (name & number)	TÜV NORD Cert, GmbH #0044 Langemarckstrasse 20 45141 Essen Germany
Certificate & number	Validity referring to MDD certificate with number: 44 232 142007

Signed on 25 May 2021. Place: Clemmons, NC Country: U.S.A.

Signature (on behalf of the manufacturer): Melissa Clark

Name of authorized signatory: Melissa Clark

Position held in the company: President