Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Multiband Ligator, for treatment of Oesophageal Varices
Basic UDI-DI:	54200513-TF05-MBL-SU-CF
Classification:	Class IIa, Rule 5
Conformity assessment route:	MDD Annex II Excluding Article 4
Models:	See attachment

G-Flex Europe SPRL declares on our own responsibility that the medical devices describe above are in conformity with the requirements of Council Directive 93/42/EEC of June 14, 1993 (MDD) as amended by Directive 2007/47/EC and of its transpositions in national laws. They are covered by an extended CE certificate in accordance with Regulation EU 2023/607 amending Regulation EU 2017/745 and are in conformity with the relevant harmonized standards EN 1041:2008/A1:2013; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; EN ISO 10993-4:2009; EN ISO 10993-11:2009; EN ISO 14644-1:2015; EN ISO 14644-2:2015; ISO 80369-7:2016.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the essential requirements of Annex I of the MDD.

Notify Body:	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp - Belgium
NB identification number:	1639
Expiry Date:	31/12/2028 as Confirmed by the Extension Letter CLNB1639 - BE/AND/23/1285.QMD
Place and date of issue:	Nivelles, 26/06/2023

G-Flex Europe SPRL - Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Thierry CREMER - QA/RA Director and PRRC

Digitally signed by Bunic Gheorghe
Date: 2024.11.02 09:05:51 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Declaration of Conformity

Attachment

Product Name: Multiband Ligator, for treatment of Oesophageal Varices

Basic UDI-DI: 54200513-TF05-MBL-SU-CF

Reference	UDI-DI	GMDN	GMDN Term
GF-OVL100	5420051301416	46680	Oesophageal endoscopic ligator, single-use
GF-OVL100-RU	5420051303755	46680	Oesophageal endoscopic ligator, single-use
GF-OVL501	5420051302444	46680	Oesophageal endoscopic ligator, single-use
GF-OVL900	5420051306749	46680	Oesophageal endoscopic ligator, single-use

Reference	UDI-DI	GMDN	GMDN Term
GF-OVL100-LC-01	4048467025279	46680	Oesophageal endoscopic ligator, single-use
GF-OVL300	5420051302642	46680	Oesophageal endoscopic ligator, single-use
GF-OVL510	5420051302635	46680	Oesophageal endoscopic ligator, single-use
GF-OVL901	5420051306763	46680	Oesophageal endoscopic ligator, single-use

Declaration of Conformity

Manufacturer:	G-Flex Europe SPRL
Single Registration Number (SRN):	BE-MF-000000623
Address:	20, Rue de l'industrie 1400 - Nivelles, Belgium
Product Name:	Reusable Multiband Ligator
Basic UDI-DI:	54200513-TF05-MBL-RU-CA
Classification:	Class I, Rule 1
Conformity assessment route:	MDR 2017/745, Annex IX excluding Chapter II
Models:	See attachment
Intended Purpose:	The Multiband Ligator is used via endoscope to ligate oesophageal varices at and above the oesophageal junction

G-Flex Europe SPRL declares on our own responsibility that the medical device describe above are in conformity with the requirements of the European Medical Device Regulation MDR 2017/745 and are in conformity with the relevant harmonized standards EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 13485:2016; EN ISO 14971:2019; EN ISO15223-1:2016; MEDDEV 2.7-1/Rev.4; ISO 2859-1:1999; EN ISO 20417:2021; ISO 17664:2017.

This statement of conformity is only valid in connection with a signed Delivery Note for the respective Lot number of produced devices.

The device fulfill the General Safety and Performance Requirements of Annex I of the MDR 2017/745

Place and date of issue: Nivelles, 07/07/2023

Thierry CREMER - QA/RA Director & PRRC

G-Flex Europe SPRL - Simple & Performing
VAT: BE0876.308.490 Certified ISO 13485

Declaration of Conformity

Attachment

Product Name: Reusable Multiband Ligator

Basic UDI-DI: 54200513-TF05-MBL-RU-CA

Reference	UDI-DI	EMDN	EMDN Description	Reference	UDI-DI	EMDN	EMDN Description
GF-OVL100-R	5420051303762	G03020301	LIGATURE SYSTEMS, OESOPHAGEAL VARICES				