

## Endo-Flex Technische Produktdatenblätter

### Oesophagus Multiband Ligator „MBL“ SU

---

**Geltungsbereich:** ENDO-FLEX

---

**Gültigkeitsdatum:** 13.12.2017

---

**Ungültig seit:**

---

**Autor:** Dirk Lemm

---

**Geprüft von:** Florian Rossa 04.12.2017  
Karin Hergert 29.11.2017  
Jens Kuehnemund 30.11.2017

---

**Genehmigt von:** Stephan Schneider 13.12.2017

---

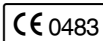
**Änderungskommentar  
zur Vorversion:**

---

## Endo-Flex Technische Produktdatenblätter

### Oesophagus Multiband Ligator „MBL“ SU

---

1. **Product Name** Oesophagus Multiband Ligator „MBL“ SU
2. **Components** ---
3. **Legal Manufacturer** ENDO-FLEX GmbH  
Alte Hünxer Str. 115  
46562 Voerde  
Germany
4. **Quality Management System** acc. to DIN EN ISO 13485
5. **Notified Body** mdc medical device certification GmbH  
Kriegerstraße 6  
70191 Stuttgart  
Germany
6. **Intended Use** The Multiband Ligator is used via endoscope to ligate oesophageal varices at and above the gastro-oesophageal junction. The Multiband Ligator is supplied non-sterile and is intended for single use only.
7. **Single Use/ Reusable** Single use
8. **Product Class acc. to MDD 93/42/EEC** IIa acc. Annex IX, Rule 5  
GMDN – Code : 34137
9. **CE Mark** 

#### 10. Dimensions

Art. No.	Details
MBL-01-06	6 shoots Multiband-Ligator

#### 11. Material

Product components	Material
Handle	POM
Cap*	ABS / Silicon
Catheter*	PTFE
Tracking wire*	Dyneema
Rings*	Latex

\* Material with patient contact

12. **Other Technical Details** see IFU
13. **Indications** The Multi-Band Ligator is used to endoscopically ligate esophageal varices at or above the gastroesophageal junction.
14. **Contraindications** The contraindications include without being limited to cricopharyngeal or esophageal narrowing/stricture, tortuous esophageal diverticula, known or suspected esophageal perforation, asymptomatic rings or webs, coagulopathy. Use of ligation bands is contraindicated in patients with a known hypersensitivity to latex.
15. **Contains Latex** yes
16. **Contains Phthalate** no

## Endo-Flex Technische Produktdatenblätter

### Oesophagus Multiband Ligator „MBL“ SU

---

**17. Supplied Sterile/ Non-sterile**



The Multi-Band Ligator is supplied non-sterile and is intended for single use only.

**18. Sterilization Method**

not applicable

**19. Packaging**

1 unit per package

**20. Packaging Material (incl. size)**

Hard Blister (65mm x 130mm x 195mm )

**21. Packaging Conditions**

Standard conditions

**22. Special Storage Conditions**

Store in a dry, cool and clean place and away from direct sunlight, heat and/or chemical fumes.

**23. Shelf life**

2 years

**24. Biocompatibility**

Acc. to EN ISO 10993