

## Konformitätserklärung

### Declaration of Conformity

Deklaracja zgodności

Wir  
 We  
 My

#### Name und Adresse des Herstellers:

Name and address of manufacturer:

nazwa i adres producenta

ENDO-FLEX GmbH

Alte Hünxer Straße 115

46562 Voerde

Germany

erklären in alleiniger Verantwortung, dass das Medizinprodukt

declare on our own responsibility that the medical device

#### Name / Produktgruppe:

Name/ Name group:

Nazwa

Gallengang-Stents SU<sup>1</sup>

Biliary Stents SU

Stenty

#### Klasse:

Class:

Klasa

IIb

#### Artikelnummer:

Article number :

Numer katalogowy

20007005	PE20011010	PE20407008	SET20107015
20007007	PE20011011	PE20407009	SET20108005
20007009	PE20011012	PE20407010	SET20108006
20007011	PE20011013	PE20407011	SET20108007
20007013	PE20011014	PE20407012	SET20108008
20007015	PE20011015	PE20407013	SET20108009
20008005	PE20107003	PE20407014	SET20108010
20008007	PE20107004	PE20407015	SET20108011
20008009	PE20107005	PE20408003	SET20108012
20008011	PE20107006	PE20408004	SET20108013
20008013	PE20107007	PE20408005	SET20108014
20008015	PE20107008	PE20408006	SET20108015
20010005	PE20107009	PE20408007	SET20110005
20010007	PE20107010	PE20408008	SET20110006
20010009	PE20107011	PE20408009	SET20110007
20010011	PE20107012	PE20408010	SET20110008
20010013	PE20107013	PE20408011	SET20110009
20010015	PE20107014	PE20408012	SET20110010
20011005	PE20107015	PE20408013	SET20110011
20011006	PE20108003	PE20408014	SET20110012
20011007	PE20108004	PE20408015	SET20110013
20011009	PE20108005	PE20410003	SET20110014
20011011	PE20108006	PE20410004	SET20110015
20011013	PE20108007	PE20410005	SET20208005
20011015	PE20108008	PE20410006	SET20208006
20108005	PE20108009	PE20410007	SET20208007
20108007	PE20108010	PE20410008	SET20208008
20108009	PE20108011	PE20410009	SET20208009
20108011	PE20108012	PE20410010	SET20208010
20108013	PE20108013	PE20410011	SET20208011
20108015	PE20108014	PE20410012	SET20208012
20110005	PE20108015	PE20410013	SET20208013
20110007	PE20110003	PE20410014	SET20208014
20110009	PE20110004	PE20410015	SET20208015
20110011	PE20110005	SET-01-08-05	SET20210005

<sup>1</sup> SU: Single use

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20110013	PE20110006	SET-01-08-07	SET20210006
20110015	PE20110007	SET-01-08-09	SET20210007
20111004	PE20110008	SET-01-08-11	SET20210008
20111005	PE20110009	SET-01-08-13	SET20210009
20111007	PE20110010	SET-01-10-05	SET20210010
20111009	PE20110011	SET-01-10-07	SET20210011
20111011	PE20110012	SET-01-10-09	SET20210012
20111013	PE20110013	SET-01-10-11	SET20210013
20111015	PE20110014	SET-01-10-13	SET20210014
PE20007003	PE20110015	SET-02-08-09	SET20210015
PE20007004	PE20111003	SET-02-10-09	XEP20007003
PE20007005	PE20111004	SET20007005	XEP20007004
PE20007006	PE20111005	SET20007006	XEP20007005
PE20007007	PE20111006	SET20007007	XEP20007006
PE20007008	PE20111007	SET20007008	XEP20007007
PE20007009	PE20111008	SET20007009	XEP20007008
PE20007010	PE20111009	SET20007010	XEP20007009
PE20007011	PE20111010	SET20007011	XEP20007010
PE20007012	PE20111011	SET20007012	XEP20007011
PE20007013	PE20111012	SET20007013	XEP20007012
PE20007014	PE20111013	SET20007014	XEP20007013
PE20007015	PE20111014	SET20007015	XEP20007014
PE20008003	PE20111015	SET20008005	XEP20007015
PE20008004	PE20208003	SET20008006	XEP20010003
PE20008005	PE20208004	SET20008007	XEP20010004
PE20008006	PE20208005	SET20008008	XEP20010005
PE20008007	PE20208006	SET20008009	XEP20010006
PE20008008	PE20208007	SET20008010	XEP20010007
PE20008009	PE20208008	SET20008011	XEP20010008
PE20008010	PE20208009	SET20008012	XEP20010009
PE20008011	PE20208010	SET20008013	XEP20010010
PE20008012	PE20208011	SET20008014	XEP20010011
PE20008013	PE20208012	SET20008015	XEP20010012
PE20008014	PE20208013	SET20010005	XEP20010013
PE20008015	PE20208014	SET20010006	XEP20010014
PE20010003	PE20208015	SET20010007	XEP20010015
PE20010004	PE20210003	SET20010008	XEP20407003
PE20010005	PE20210004	SET20010009	XEP20407004
PE20010006	PE20210005	SET20010010	XEP20407005
PE20010007	PE20210006	SET20010011	XEP20407006
PE20010008	PE20210007	SET20010012	XEP20407007
PE20010009	PE20210008	SET20010013	XEP20407009
PE20010010	PE20210009	SET20010014	XEP20407010
PE20010011	PE20210010	SET20010015	XEP20407011
PE20010012	PE20210011	SET20107005	XEP20407013
PE20010013	PE20210012	SET20107006	XEP20407015
PE20010014	PE20210013	SET20107007	XEP20410003
PE20010015	PE20210014	SET20107008	XEP20410004
PE20011003	PE20210015	SET20107009	XEP20410005
PE20011004	PE20210017	SET20107010	XEP20410006
PE20011005	PE20407003	SET20107011	XEP20410007
PE20011006	PE20407004	SET20107012	XEP20410010
PE20011007	PE20407005	SET20107013	XEP20410011

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PE20011008      PE20407006      SET20107014      XEP20410013  
PE20011009      PE20407007

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG Anhang I entspricht.  
meets all applicable requirements of the Directive 93/42/EEC Annex I.

spełnia wszystkie przepisy dyrektywy 93/42/EWG Aneks I

**Benannte Stelle:**

*Notified body:*

Jednostka notyfikowana

mdc medical device certification GmbH  
Kriegerstraße 6  
70191 Stuttgart  
Germany  
0483

**Konformitätsbewertungsverfahren:**

*Conformity assessment procedure:*

oświadczamy na swoją własną odpowiedzialność, że wyrób medyczny

Richtlinie 93/42/EWG, Anhang II ohne (4)  
Directive 93/42/EEC, Annex II excluding (4)

**Zertifikatsnummer :**

*Certificate No. :*

nr certyfikatu

**Erstmalige CE-Kennzeichnung:**

*first CE mark:*

Pierwsze oznakowanie CE

**Gültig bis:**

*Valid until:*

ważny do

Voerde 29.04.2021

ENDO-FLEX GmbH

D1033500044

1997

26.05.2024



Jens Kühnemund  
Sicherheitsbeauftragter  
Safety Representative