

EC CERTIFICATE

Number: 2001334CE05

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

Freudenberg Medical, LLC

1110 Mark Ave.

Carpinteria Ca 93013-2918

United States Of America

For the product category(ies)

Adjustable Bi-Flanged Fistula Prosthesis with insertion and removal catheter for management of hypopharyngeal fistulae

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2001334CN, initially dated 31 March 2000

Addendum, initially dated 18 February 2014

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 April 2023
Issued for the first time: 18 February 2014
Revised: 18 October 2015
Reissued: 1 April 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2001334CE05

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Adjustable Bi-Flanged Fistula Prosthesis with insertion and removal catheter for management of hypopharyngeal fistulae

Issued to:

Freudenberg Medical, LLC

**1110 Mark Ave.
Carpinteria Ca 93013-2918
United States Of America**

This certificate covers the following product(s):

Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis (25mm, 38mm and 50mm) (Class IIa)
Blom-Singer® Insertion and Removal Catheter (Class IIa)

Initial date: 18 February 2014

Revision date: 24 March 2014

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, consisting of a stylized 'Z' followed by 'oetbrood'.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, consisting of a stylized 'L' followed by 'aan'.

ing. A.A.M. Laan
Certification Manager

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