

# EC CERTIFICATE

Number: 2001334CE01

## 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)

**Silicone Otorhinolaryngology Devices**

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

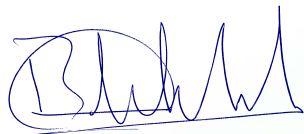
Documents, that form the basis of this certificate:

**Certification Notice 2001334CN, initially dated 31 March 2000**  
**Addendum, initially dated 17 April 2003**

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: 31 March 2000  
Revised: 18 October 2015  
Reissued: 1 April 2018

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2001334CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Silicone Otorhinolaryngology Devices

Issued to:

### Freudenberg Medical, LLC

1110 Mark Ave.  
Carpinteria, CA 93013-2918  
United States Of America

This certificate covers the following product(s):

#### Indwelling Voice Protheses (Class IIb)

- Advantage Indwelling Voice Prothesis (non-sterile), 16F & 20F, 4-14mm
- Classic Indwelling Voice Prothesis (sterile & non-sterile), 16F & 20F, 4-20mm
- Large Esophageal Flange Hard Valve Indwelling Voice Prothesis (sterile), 22.5F, 6-12mm
- Dual Valve Indwelling Voice Prothesis (non-sterile), 20F, 6-14mm

#### Patient Changeable Voice Protheses (Class IIb)

- Duckbill Voice Prothesis (non-sterile), 16F, 6-18mm
- Low Pressure Voice Prothesis (non-sterile), 16F & 20F, 4-28mm non-sterile

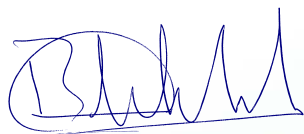
TEP Occluders (non-sterile), 16F & 20F, 4-14mm (Class IIb)

Laryngectomy Tubes (sterile & non-sterile), 12-17mm x 36-55mm (Class IIb)

Initial date: 17 April 2003

Revision date: 3 February 2021

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396