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

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
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ADDENDUM

Belonging to certificate: 2001334CE01

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

Patient Changeable Voice Prostheses (Class IIb)
- Duckbill Voice Prosthesis (non-sterile), 16F, 6-18mm
- Low Pressure Voice Prosthesis (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

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