

CERTIFICATE

Number: 3820944

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Freudenberg Medical, LLC

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

Manufacturer Facility Identifier F000558

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design/contract design, manufacture and distribution of voice prostheses, laryngectomy tubes, tracheostoma products, heat/moisture exchangers and attachment housings; ENT surgical procedure kits; nasal septal devices; ENT foreign body extractors; fistula occluders for the area of otolaryngology. Design/contract design, manufacture/contract manufacture and distribution of silicone components and finished goods for anesthesiology, cardiovascular, gastroenterology, neurology, nephrology, oncology, ophthalmology, orthopedics, otolaryngology, plastic surgery and urology.

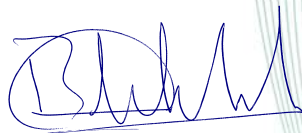
Certificate expiry date: 1 April 2022

Certificate effective date: 6 April 2021

Certified since: 14 December 2018

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

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

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:

<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 3820944

The management system of the organization(s) and/or location(s) of:

Freudenberg Medical, LLC

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

Certified organization(s) and/or locations:

Freudenberg Medical, LLC
6385 Rose Lane, Suite A
(Building #3)
Carpinteria, CA 93013
Manufacturer Facility Identifier F000558

Receiving / Receiving Inspection and Raw Material Warehouse

Freudenberg Medical, LLC
1110 Mark Avenue
(Building# 1)
Carpinteria, CA 93013
Manufacturer Facility Identifier F000558

Design/contract design, manufacture and distribution of voice prostheses, laryngectomy tubes, tracheostoma products, heat/moisture exchangers and attachment housings; ENT surgical procedure kits; nasal septal devices; ENT foreign body extractors; fistula occluders for the area of otolaryngology. Design/contract design, manufacture/contract manufacture and distribution of silicone components and finished goods for anesthesiology, cardiovascular, gastroenterology, neurology, nephrology, oncology, ophthalmology, orthopedics, otolaryngology, plastic surgery and urology

ADDENDUM

To certificate: 3820944

The management system of the organization(s) and/or location(s) of:

Freudenberg Medical, LLC

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

Freudenberg Medical, LLC
1009 Cindy Lane
(Building# 2)
Carpinteria, CA 93013
Manufacturer Facility Identifier F000558

Design/contract design, manufacture and distribution of voice prostheses, laryngectomy tubes, tracheostoma products, heat/moisture exchangers and attachment housings; ENT surgical procedure kits; nasal septal devices; ENT foreign body extractors; fistula occluders for the area of otolaryngology. Design/contract design, manufacture/contract manufacture and distribution of silicone components and finished goods for anesthesiology, cardiovascular, gastroenterology, neurology, nephrology, oncology, ophthalmology, orthopedics, otolaryngology, plastic surgery and urology.

Addendum expiry date: 1 April 2022
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