

CERTIFICATE

Number: 3820944

The management system of:

Freudenberg Medical, LLC

1110 Mark Ave.

Carpinteria, CA 93013-2918

United States Of America

Manufacturer DUNS 120981337

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 accessories; 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.

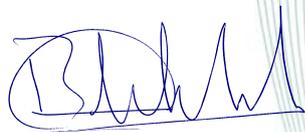
This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

Certificate expiry date: 2021-12-14

Certificate effective date: 2018-12-14

Certified since: 2018-12-14

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/certified-organizations>

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



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ADDENDUM 1/1

To certificate: **3820944**

concerning the Management System of:

Freudenberg Medical, LLC

List of certified locations:

Location	Certification scope
Freudenberg Medical, LLC (Building# 1) 1110 Mark Avenue Carpinteria, CA 93013 USA	Design/contract design, manufacture and distribution of voice prostheses, laryngectomy tubes, tracheostoma products, heat/moisture exchangers and accessories; 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.
Freudenberg Medical, LLC (Building# 2) 1009 Cindy Lane Carpinteria, CA 93013 USA	Design/contract design, manufacture and distribution of voice prostheses, laryngectomy tubes, tracheostoma products, heat/moisture exchangers and accessories; 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.
Freudenberg Medical, LLC (Building #3) 6385 Rose Lane, Suite A Carpinteria, CA 93013 USA	Receiving / Receiving Inspection and Raw Material Warehouse

Addendum Initial date: 2018-12-14

Addendum effective date: 2018-12-14