

CERTIFICATE

Number: 3818973

The management system of:

Freudenberg Medical, LLC

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

including the implementation meets the requirements of the standard:

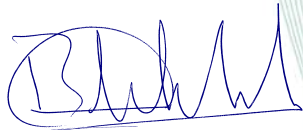
EN ISO 13485:2016

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.

Certificate expiry date: 14 December 2021
Certificate effective date: 14 December 2018
Certified since: 23 March 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



ADDENDUM 1/1

To certificate: **3818973**

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: 23 March 2018

Addendum effective date: 14 December 2018