

CERTIFICATE

Number: 3818973

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

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

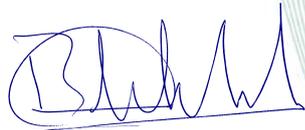
Scope:

Design/contract design, manufacture and distribution of voice prostheses, laryngectomy tubes, tracheostoma products, heat/moisture exchangers and 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: 01 April 2024
Certificate effective date: 06 April 2021
Certified since: 23 March 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



ADDENDUM

To certificate: 3818973

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
1009 Cindy Lane
(Building# 2)
Carpinteria, CA 93013

Different 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.

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

Receiving / Receiving Inspection and Raw Material Warehouse

Freudenberg Medical, LLC
1110 Mark Avenue
(Building# 1)
Carpinteria, CA 93013

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: 01 April 2024

Addendum effective date: 06 April 2021