

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

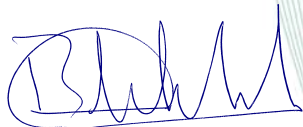
Scope:

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: 1 April 2027
Certificate effective date: 1 April 2024
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.M. McKenzie
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:

Different scope

Freudenberg Medical, LLC
1110 Mark Ave. (Building #1)
Carpinteria, CA 93013-2918
United States Of America

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
1009 Cindy Lane (Building #2)
Carpinteria, CA 93013
United States Of America

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
6385 Rose Ln, Ste A (Building #3)
Carpinteria, CA 93013-2941
United States Of America

Receiving / Receiving Inspection and Raw Material Warehouse

Addendum expiry date: 1 April 2027
Addendum effective date: 1 April 2024