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

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.

MDSAP
MEDICAL DEVICE 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
Addendum effective date: 6 April 2021