

CERTIFICATE

Number: 3811707

The management system of:

Freudenberg Medical, LLC

1110 Mark Ave.
Carpinteria CA, 93013-2918
USA

including the implementation meets the requirements of the standard:

EN ISO 13485:2012 + AC:2012

Scope:

Design, manufacture and distribution of otorhinolaryngology dressings, sinus stents, laryngectomy tubes, tracheoesophageal puncture devices, tracheostoma valves, filter sets, voice prostheses, insufflation test sets and silicone tubing, silicone stoppers and silicone gaskets. In addition, contract manufacturing services including extrusion, molding, and assembly of components and distribution of finished goods for the anaesthesiology, cardiovascular, ENT, gastroenterology, neurology, nephrology, ophthalmology, orthopaedics, plastic surgery and urology medical device industry

Certificate expiry date: 31 March 2018
Certificate effective date: 11 September 2017
Certified since: 11 February 2015

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM 1/1

to Certificate: **3811707**

concerning the Management System of:

Freudenberg Medical, LLC

1110 Mark Ave.
Carpinteria, CA 93013-2918
USA

List of certified locations:

Location	Certification scope
Freudenberg Medical, LLC (Building# 1) 1110 Mark Avenue Carpinteria, CA 93013 USA	Design, manufacture and distribution of otorhinolaryngology dressings, sinus stents, laryngectomy tubes, tracheoesophageal puncture devices, tracheostoma valves, filter sets, voice prostheses, insufflation test sets and silicone tubing, silicone stoppers and silicone gaskets. In addition, contract manufacturing services including extrusion, molding, and assembly of components and distribution of finished goods for the anaesthesiology, cardiovascular, ENT, gastroenterology, neurology, nephrology, ophthalmology, orthopaedics, plastic surgery and urology medical device industry.
Freudenberg Medical, LLC (Building# 2) 1009 Cindy Lane Carpinteria, CA 93013 USA	Design, manufacture and distribution of otorhinolaryngology dressings, sinus stents, laryngectomy tubes, tracheoesophageal puncture devices, tracheostoma valves, filter sets, voice prostheses, insufflation test sets and silicone tubing, silicone stoppers and silicone gaskets. In addition, contract manufacturing services including extrusion, molding, and assembly of components and distribution of finished goods for the anaesthesiology, cardiovascular, ENT, gastroenterology, neurology, nephrology, ophthalmology, orthopaedics, plastic surgery and urology medical device industry.
Freudenberg Medical, LLC (Building #3) 6385 Rose Lane, Suite A Carpinteria, CA 93013 USA	Receiving / Receiving Inspection and Raw Material Warehouse

Addendum Initial date: February 11, 2015
Addendum Effective date: September 11, 2017