

CERTIFICATE

Number: **560023**

The management system of:

Freudenberg Medical, LLC

1110 Mark Ave.
Carpinteria, CA 93013-2918
USA

including the implementation meets the requirements of the standard:

ISO 13485:2003

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.

This certification also includes the location as identified on the Addendum belonging to this Certificate.

Certificate expiry date: **March 31, 2018**
Certificate effective date: October 18, 2015
Certified since: March 31, 2000

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is a CMDCAS recognized registrar.
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ADDENDUM 1/1

To certificate: **560023**

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, 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 7301 East 90th Street, Suite 100 Indianapolis, IN 46256 USA	Design and development of otorhinolaryngology devices and accessories.

Addendum Initial date: December 19, 2003

Addendum effective date: October 18, 2015