

CERTIFICATE

Number: 560023.001

The management system of:

Helix Medical LLC

Also trading as InHealth Technologies

1110 Mark Avenue
Carpinteria CA 93013-2918
USA

including the implementation meets the requirements of the standard:

ISO 13485:2003

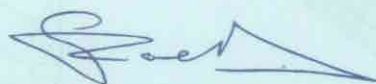
Scope:

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.

This Certificate is valid for the facilities as mentioned on the Addendum with identification 560023.001

Certificate expiry date: March 31, 2012
Certificate effective date: March 30, 2010
Certified for the first time: March 31, 2000

KEMA Quality B.V.



drs. G.J. Zoetbrood
Managing Director



M. McCann
Certification Manager

Accredited by:
Standards Council of Canada

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ADDENDUM

To Certificate 2001334

Concerning the management system of:

Helix Medical LLC

Also trading as InHealth Technologies

1110 Mark Avenue
Carpinteria, CA 93013-2918
USA

List of additional design, manufacturing and distribution locations:

InHealth Technologies
1009 Cindy Lane
Carpinteria, CA 93013
USA

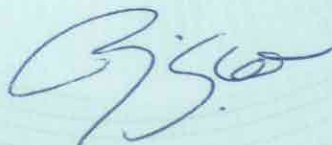
InHealth Technologies
1015 Cindy Lane
Carpinteria, CA 93013
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