

789 North Dixboro Road, Ann Arbor, Michigan 48105
(888) NSF-9000

Certificate of Registration

This certifies that the Quality Management System of
Helix Medical LLC, Gloucester

92 Blackburn Center
Gloucester, Massachusetts, 01930, United States

has been assessed by NSF-ISR and found to be in conformance to the following standard(s):

ISO 13485:2003

Scope of Registration:

The molding, fabrication and assembly of liquid silicone products for healthcare applications

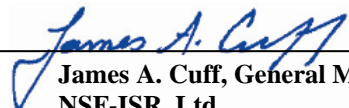
Exclusions: 7.3 Product Design, 7.5.1 Service, 7.5.1.2.1, 7.5.1.2.2, 7.5.1.2.3, 7.5.1.3, 7.5.2.2

Industrial Classification:

NACE: DH 25.2
IAF - QMS: 14, 40

Certificate Number: C0045053-MD1
Certificate Issue Date: 23-JUN-2010
Registration Date: 23-JUN-2010
Expiration Date *: 22-JUN-2013




James A. Cuff, General Manager
NSF-ISR, Ltd.