



Product Service

CERTIFICATE

No. Q2N 14 10 90009 001

Holder of Certificate: Lake Region Medical

3902 California Road
Orchard Park NY 14127
USA

Certification Mark:



Scope of Certificate: Contract Production of Metal Machined Parts,
Metal Injection Molded Parts,
Clean Room Processing,
Cleaning, Packaging and Labeling.
See attachment for details

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: NM1409723

Valid from: 2014-12-05
Valid until: 2017-12-04



Hans-Heiner Junker

Date, 2014-12-10

Page 1 of 3





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No. Q2N 14 10 90009 001

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

Facility(ies): Lake Region Medical
3902 California Road, Orchard Park NY 14127, USA

Lake Region Medical
3176 Abbott Road, Orchard Park NY 14127, USA



Attachment for Certificate no Q2N 14 10 90009 001
valid from 2014-12-05



Product Service

Supplement 001 dated 2014-12-05 (NM1306995)

Facility(ies):

Lake Region Medical (90009)
3902 California Road
Orchard Park, NY 14127 USA

Products / Product Categories:

Contract Production of Metal Machined Parts and Clean Room Processing,
Cleaning, Packaging and Labeling

Lake Region Medical (90096)
3176 Abbott Road
Orchard Park, NY 14127 USA

Products / Product Categories:

Contract Production of Metal Injection Molded Parts and Cleaning and Labeling

Munich, CRT2, 2014-12-10

Hans-Heiner Junker

