

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Degania Medical Devices Pvt Ltd  
Plot No. 251 & 275  
Sector 6, IMT Manesar  
Gurgaon 122 050  
Haryana  
India

Holds Certificate No:

**MD 670377**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

1. Contract Manufacture, Assembly, Packaging and ETO Sterilization of Silicone Medical Devices.
2. Contract Manufacture, Assembly, Packaging of Vascular and Cardiovascular Medical Devices.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-11-30

Latest Revision Date: 2018-06-08

Effective Date: 2017-04-07

Expiry Date: 2019-02-28

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...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](http://www.bsi-global.com/ClientDirectory).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +91 11 2692 9000.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

# CERTIFICATE

Management system as per  
**ISO 14001 : 2004**

In accordance with TÜV NORD CERT procedures, it is hereby certified that

**DEGANIA MEDICAL DEVICES PVT. LIMITED**  
Unit 1: Plot No. 251, Sector-6, IMT Manesar, Gurgaon,  
Unit 2: Plot No. 275, Sector-6, IMT Manesar,  
Gurgaon - 122 050, Haryana,  
India



applies a management system in line with the above standard for the following scope

**Contract Manufacture, Assembly, Packaging and ETO Sterilization  
of Silicone Medical Devices. Contract Manufacture of Components  
for Vascular and Cardiovascular Medical Devices.  
The Manufacture of Surgical Drapes and Covers.**

Certificate Registration No. **44 104 15390635**  
Audit Report No. **2.5-5425/2012**

Valid until **14.09.2018**  
(Until **25.06.2019** in case of transition to ISO 14001:2015)



Certification Body  
at TÜV NORD CERT GmbH

Issue **26.06.2016**  
Place : **Mumbai**

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD CERT GmbH

Langemarckstrasse 20

45141 Essen

[www.tuev-nord-cert.com](http://www.tuev-nord-cert.com)

TUV India Pvt. Ltd., 801, Raheja Plaza – 1, L.B.S. Marg, Ghatkopar (W), Mumbai - 400 086, India [www.tuv-nord.com/in](http://www.tuv-nord.com/in)



# CERTIFICATE

Management system as per  
**BS OHSAS 18001 : 2007**

In accordance with TÜV NORD CERT procedures, it is hereby certified that

**DEGANIA MEDICAL DEVICES PVT. LIMITED**  
Unit 1: Plot No. 251, Sector-6, IMT Manesar, Gurgaon,  
Unit 2: Plot No. 275, Sector-6, IMT Manesar,  
Gurgaon - 122 050, Haryana,  
India



applies a management system in line with the above standard for the following scope

**Contract Manufacture, Assembly, Packaging and ETO Sterilization  
of Silicone Medical Devices. Contract Manufacture of Components  
for Vascular and Cardiovascular Medical Devices.  
The Manufacture of Surgical Drapes and Covers**

Certificate Registration No. **44 116 16391027**  
Audit Report No. **2.5-5425/2012**

Valid until **25.06.2019**



Certification Body  
at TÜV NORD CERT GmbH

Issue **26.06.2016**  
Place : **Mumbai**

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD CERT GmbH

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