

Intertek



Certificate of Registration

The following organization's quality management system has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

ISO 13485:2003

Certificate Number
065 C

Initial Certification Date
02 August 2005

Certificate Issue Date
15 August 2012

Certificate Expiry Date
08 August 2015

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the accredited body.

AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited.

AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061.

In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.

AMTAC Certification Services Limited
Davy Avenue
Knowlhill
Milton Keynes
MK5 8NL, UK
☎ Telephone
+44 (0)1908 857 750
Email: acsl@intertek.com

Organization:

DEGANIA SILICONE LIMITED

Degania Bet 15130, Israel

The Quality Management System is applicable to
Design, manufacture and inspection of:
Sterile and non-sterile silicone based medical devices.



0061

Authorised Signatory:

AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd



Intertek

Certificate of Registration

This is to certify that the quality management system of

Degania Silicone Limited

Main Site: Degania Bet, 15130, Israel

has been assessed and registered by Intertek, a CMDCAS recognized registrar, as conforming to the requirements of

ISO 13485:2003

The quality management system is applicable to:

The Design, Manufacture and Inspection of Medical Silicone devices: Vessel loops, Vessel paws, Foley Catheters, 3 Way Irrigation Catheters, Temperature Sensor Catheters, Tiemann Catheters, Suprapubic Catheters, Gastrostomy Replacement Tubes, Surgical Drains, Closed Wound Drainage System, Silicone tubing, Silk Silicone Sheet, Tourniquets, Nipple Shields, Reservoir bulbs.



Certificate Number: 9485-5

Initial Certification Date: 21 May 2012

Certificate Effective Date: 21 May 2012

Certificate Expiry Date: 21 May 2015

Colin Mabbey - President, Systems Certification
Intertek Testing Services NA Ltd. - Lachine, QC, Canada

Intertek Testing Services NA Ltd. - Lachine, QC, Canada

Intertek



Certificate of Registration

The following organization's quality management system has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

ISO 9001:2008

Certificate Number
065

Initial Certification Date
30 October 1997

Certificate Issue Date
15 August 2012

Certificate Expiry Date
08 August 2015

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the accredited body.

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+44 (0)1908 857 750
Email: acsl@intertek.com

Organization:

DEGANIA SILICONE LIMITED

Degania Bet 15130, Israel

The Quality Management System is applicable to
Design, manufacture and inspection of:
Sterile and non-sterile silicone based medical devices.
Non-medical silicone products

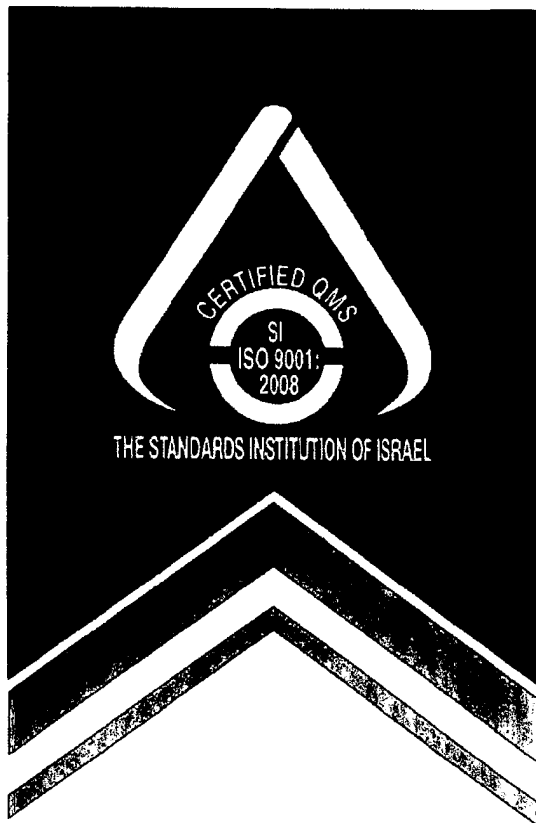


0061

Authorised Signatory:

AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd



Certificate

This is to certify that the
Quality Management System
of

DEGANIA SILICONE LTD.

DEGANIA BET, ISRAEL

has been audited by SII and found to comply with the Quality Management Standard SI ISO 9001: 2008

scope:

DESIGN AND PRODUCTION OF SILICONE RUBBER FOR
MEDICAL AND INDUSTRIAL PURPOSES.

The Certificate is granted in accordance with SII's Rules for the Certification of Quality Systems (SII procedure-002). The validity of the Certificate is subject to the continuous maintenance of the Quality System according to the above standard, and the follow-up surveillance performed by SII. Further clarifications regarding the scope of the certificate and applicability of ISO 9001:2008 requirements may be obtained by consulting the organization.

Date of initial approval: 01 . 04 . 1990
Date of expiration: 14 . 12 . 2013

License No: 60198
Date of issue: 24 . 10 . 2010

www.sii.org.il

THE STANDARDS INSTITUTION OF ISRAEL



Daniel Goldstein
Daniel Goldstein
Director General



וזאת
לתעודה
כי
מערכת ניהול האיכות של



דגניה סיליקון בע"מ

דגניה כ.

נבחנה ונסקרה על ידי מכון התקנים הישראלי ונמצאה מתאימה
לדרישות התקן הישראלי והתקן הבין-לאומי ת"י ISO 9001 : 2008

תחום :

תיכון (פיתוח) וייצור של מוצרי גומי סיליקון
לתחום הרפואי והתעשייתי.

אישור זה ניתן בהתאם לכללים לאישור מערכות ניהול איכות (נוהל מת"י 002) שאושרו על ידי המכון.
תוקף האישור מותנה בתחזוקה שוטפת של מערכת האיכות בהתאם לדרישות התקן הנ"ל ובצוע פקוח ע"י מת"י.
הבהרות נוספות הנוגעות לתחום האישור ולקיום דרישות התקן ת"י ISO 9001 מהדורת 2008 ניתן לקבל מהארגון

מס היתר : 60198
תאריך הוצאת אישור זה : 24 . 10 . 2010

תאריך האישור הראשון : 01 . 04 . 1990
תאריך פקיעת אישור זה : 14 . 12 . 2013

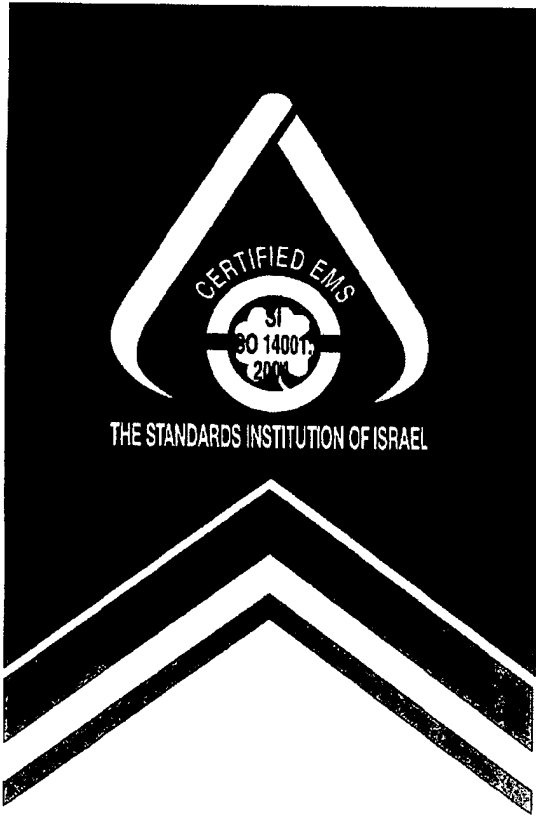
www.sii.org.il



דניאל גולדשטיין
המנהל הכללי



מכון התקנים הישראלי



Certificate

This is to certify that the
Environmental Management System
of

DEGANIA SILICONE LTD.

DEGANIA BET, ISRAEL

has been audited by SII and found to comply with the Environmental Management Standard SI ISO 14001:2004

scope:

*DESIGN AND PRODUCTION OF SILICONE RUBBER FOR
MEDICAL AND INDUSTRIAL PURPOSES.*

The Certificate is granted in accordance with SII's Rules for the Certification of Environmental Management Systems (SII procedure-009). The validity of the Certificate is subject to the continuous maintenance of the System according to the above standard, and the follow-up surveillance performed by SII.

651E (05/10)

Date of initial approval: 03 . 06 . 2008
Date of expiration: 14 . 12 . 2013

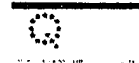
License No: 45425
Date of issue: 14 . 10 . 2010

www.sii.org.il

THE STANDARDS INSTITUTION OF ISRAEL



Daniel Goldstein
Daniel Goldstein
Director General



וזאת לתעודה

כי
מערכת הניהול הסביבתי של



דגניה סיליקון בע"מ

דגניה ב.
נבחנה ונסקרה על ידי מכון התקנים הישראלי ונמצאה מתאימה
לדרישות התקן הישראלי והתקן הבין-לאומי ת"י ISO 14001:2004

תחום:
תיכון (פיתוח) וייצור של מוצרי גומי סיליקון
לתחום הרפואי והתעשייתי.

אישור זה ניתן בהתאם לכללים לאישור מערכות ניהול סביבתי (נוהל מת"י 009) שאושרו על ידי המכון.
תוקף האישור מותנה בתחזוקה שוטפת של המערכת בהתאם לדרישות התקן הנ"ל ובצוע פקוח ע"י מת"י.

מספר היתר: 45425
תאריך הוצאת אישור זה: 14. 10. 2010

תאריך האישור הראשוני: 03. 06. 2008
תאריך פקיעת אישור זה: 14. 12. 2013

05-1011111



דניאל גולדשטיין
המנהל הכללי



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מכון התקנים הישראלי

Intertek

Certificate Number
065.1 CE

Initial Certification Date
30 October 1997

Certificate Issue Date
26 October 2012

Certificate Expiry Date
29 October 2017

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

AMTAC Certification Services Limited
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MK5 8N, UK
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EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices,
Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

Organization:

DEGANIA SILICONE LIMITED

Degania Bet 15130, Israel

See attached schedule

Authorized Signatory



AMTAC Certification Services Limited, Milton Keynes, UK

**PRODUCT SCHEDULE FOR CERTIFICATE 065.1 CE
DEGANIA SILICONE LIMITED**

Identiloops	Mini Maxi Super Maxi
Silclamps	Small Medium Large
Foley Catheters	Various
3 Way Irrigation Catheters	
Temperature Sensor Catheter	
Tiemann Catheters	
Suprapubic Catheters	
Gastrostomy Replacement Tubes / Gastronomy Button	
Surgical Drains	Easy Flow Drains Round Drains Flat Drains Dual Sump Drains Multi Lumen Drains Fluted Drains
Closed Wound Drainage System	
Silclear Tubings	

Original Issue Date: 30 October 1997

Authorized Signatory:



Certificate Issue Date: 26 October 2012

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EC Certification



PRODUCTION QUALITY ASSURANCE
Directive 93/42/EEC for Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions - has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

DEGANIA SILICONE LIMITED

Degania Bet 15130, Israel

Class 1 Sterile Silicone disposable medical devices as per the attached schedule.

Certificate Number: 065 CE
Initial Certification Date: 30 October 1997
Certificate Effective Date: 18 April 2013
Certificate Expiry Date: 29 October 2017

Brian Johnson ~ Authorised Signatory

AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd a wholly owned subsidiary of Intertek Holdings Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.
AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.
AMTAC Certification Services Limited, Davy Avenue, Knowlhill, Milton Keynes, MK5 8NL, UK ☎ Telephone +44 (0)1908 857 750 Email: acsl@intertek.com

Intertek Intertek Intertek Intertek Intertek

**PRODUCT SCHEDULE FOR CERTIFICATE 065 CE
DEGANIA SILICONE LIMITED**

Intertek

**Reservoir (bulb)
Sterile needle-less pre-filled syringe for catheter balloon inflation**



**Initial Certification Date: 30 October 1997
Certificate Effective Date: 18 April 2013**

Brian Johnson ~ Authorized Signatory

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