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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

Degania Silicone Limited
Kibbutz
1513000 DEGANIA BET
ISRAEL

Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
041538	713335291	Ravi.Ha@tuvsud.com	-	2024-04-17	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 041538 0012 Rev. 00

Reference: 713335291

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: IL-MF-000010009

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 041538 0012 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-17

TÜV SÜD Product Service GmbH
Medical and Health Services

Ravi H A
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Apr 17, 2024 11:22 GMT+2)

Michael Mauermeir
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
3 Way Irrigation Catheter **Basic UDI-DIs:** **72900016011023WIR5Z** **72900016013WNSSH**	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Easy flow and Multilumen **Basic UDI-DIs:** **7290001607EFNSVM** **7290001607201EFBE**	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Foley Catheter 2 way **Basic UDI-DI:** **72900016011012WF3K**	☒ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Gastrostomy Jejunal Replacement Tube **Basic UDI-DI:** **7290000846302GJTCX**	☒ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Gastrostomy Replacement Tube **Basic UDI-DI:** **7290000846303GRTDW**	☒ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Identi loops **Basic UDI-DI:** **7290001603IDLNST8** **7290001603401IDL7V**	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Low-Profile Gastrostomy Tube/Button Kit **Basic UDI-DI:** **7290001605303GBB7**	☒ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Naso-Gastric Tube **Basic-UDI-DI:** **7290000846301NGEU**	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Round Flat and Fluted Drains **Basic UDI-DIs:** **7290001607202DRC8**	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
7290001607202DRSAD **7290001607DRNSXA** **7290001607CWDSNVU** **7290001607CWDSSW6**			
Silclamps **Basic UDI-DIs:** **7290001603404SCC3** **7290001603SCNSWU**	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Silicone tubing **Basic UDI-DIs:** **7290001604501STDE** **7290001604STNSZU**	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
TSC - Temperature Sensor catheter **Basic UDI-DIs:** **7290001601104TSC8T**	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 041538 0005 Rev.00 NB#0123
Stoma measuring device **Basic UDI-DIs:** **7290001603V300SMDR3**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: G2S 041538 0006 Rev.00 NB#0123
Extension Feeding Set **Basic UDI-DIs:** **7290001609304EXE6** **7290001609EXNSZ5**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: G2S 041538 0006 Rev.00 NB#0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable			

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-17	713335291	Initial issue

Degania Silicon LTD.
Degania Bet, Jorden Valley
Israel 1513
Phone: +972-4675-5100
E-mail:ds@ds-il.com

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Degania Silicone Ltd.
Manufacturer address and contact details	Degania Bet, 1513000, Israel
Single Registration Number (SRN) (if available)	IL-MF-000010009

Authorised Representative name (if applicable)	Biometrix SRO
Authorised Representative address and contact details	Vicenzy 16, Samorin 93101, Slocakia
Single Registration Number (SRN) (if available)	SK-AR-000002253

Notified body name (if applicable)	TUV SUD Product Service GmbH See attached schedule
Notified body number (if applicable)	0123 See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Degania Silicon LTD.
Degania Bet, Jorden Valley
Israel 1513
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Directive Certificate number(s) to which this confirmation is made (if applicable)	G2S 0415385 006 Rev.00 G1 041538 0005 Rev.00 See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024 See attached schedule
End date of extended validity/transition period	31 Dec 2028 See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

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- **Quality Management System (QMS)**

  Choose one applicable statement:

  - ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
  - ☒ A QMS in accordance with Article 10(9) MDR is in place.
  - ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

  - The device(s) continue to comply with the AIMDD or MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Degania Silicone Ltd.

Israel, July 24, 2023

Tali Raz, QA/RA Director

traz@qmd.net

Degania Silicone Ltd
Degania Bet 1513000

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Phone: +972-4675-5100
E-mail:ds@ds-il.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Foley Catheter 2 way	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
3 Way Irrigation Catheter	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Suprapubic Catheter	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
TSC - Temperature Sensor catheter	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Easy flow and Multilumen	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Round Flat and Fluted Drains	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Naso-Gastric Tube	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Gastrostomy Replacement Tube	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Gastrostomy Jejunal Replacement Tube	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Low-Profile Gastrostomy Tube/Button Kit	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Identi loops	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Silclamps	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Silicone tubing	G1 041538 0005	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Extension Set	G2S 0415385 006	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A
Stoma measuring device	G2S 0415385 006	26 May 2024	TÜV SÜD 0123	TÜV SÜD 0123	31 December 2028	N/A

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 041538 0005 Rev. 00

Manufacturer: **Degania Silicone Limited**
Kibbutz
1513000 Degania Bet
ISRAEL

Product Category(ies): **Identiloops, Silclamps, Urological Catheters and kits with accessories, Gastrostomy & Feeding Tubes and kits with accessories, Surgical Drains and kits with accessories, Sterile and non-sterile medical devices for general surgery, chest drainage and custom made medical device components**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: IND2019062

Valid from: 2019-10-17
Valid until: 2024-05-26

Date, 2019-10-17

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4-/ 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 041538 0005 Rev. 00

Facility(ies):

Degania Silicone Limited
Kibbutz, 1513000 Degania Bet, ISRAEL

Shomrat Molds LTD
Industrial Zone, 1030000 Hatzor Haglilit, ISRAEL

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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