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DECLARATION OF CONFORMITY TO THE MEDICAL DEVICE DIRECTIVE

MDD 93/42EEC as amended by 2007/47EC

Authorized Representative.

Biometrix SRO
Vicenzy 16S
Samorin, 93101
Slovakia
SRN: SK-AR-000002253

Notified body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 MÜNCHEN
Germany
Notified Body number: 0123

Manufacturer Name and Address:

Degania Silicone Ltd
Degania bet, 1513000
Israel
SRN: IL-MF-000010009

Importer:

Biometrix SRO
Vicenzy 16S
Samorin, 93101
Slovakia
SRN:SK-IM-000003112

Certificate No: G1 041538 0005 **(Exp. Date)**:26/05/2024

Product family: Surgical accessories

Products sub-groups: Identi loops

Classification:Class IIa, Rule 7

Intended Use: Useful in operating room situations requiring retraction, identification, or occlusion of arteries, veins, nerves, tendons or ureters

GMDN Code: 61916

CND Code: C019010

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Applicable Standards: 11-005 REV01 list of standards TF 4.01

Herewith to declare that:
Above-mentioned product complies with Annex II excluding 4 of the Medical Device Directive, MDD 93/42/EEC as amended by 2007/47/EC. All supporting documentation is held by the manufacturer.
Degania Silicone Ltd is exclusively responsible for the Declaration of Conformity.

List of devices is enclosed in Appendix A.

DocuSigned by:
Tali Raz
80384192B292421...

28.03.2022

RA Manager | Date

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Appendix A - List of devices:

Catalog No	Description
231020371XX	Id- loops mini yellow 50m roll
231020473XX	Id- loops mini yellow 50m dram
231021280XX	Id- loops mini yellow 18" sterile
231030371XX	Id- loops mini blue 50m roll
231030473XX	Id- loops mini blue 50m dram
231031280XX	Id- loops mini blue 50m dram
231040371XX	Id- loops mini blue 18" sterile
231040473XX	Id- loops mini white 50m roll
231041280XX	Id- loops mini white 50m dram
231050371XX	Id- loops mini white 18" sterile
231050473XX	Id- loops mini red 50m roll
231052180XX	Id- loops mini red 18" sterile
231120371XX	Id- loops maxi yellow 50m roll
231120473XX	Id- loops maxi yellow 50m dram
231121280XX	Id- loops maxi yellow 18" sterile
231130371XX	Id- loops maxi blue 50m roll
231130473XX	Id- loops maxi blue 50m dram
231131280XX	Id- loops maxi blue 18" sterile
231140371XX	Id- loops maxi white 50m roll
231140473XX	Id- loops maxi white 50m dram
231141280XX	Id- loops maxi white 18" sterile
231150371XX	Id loops maxi red 50m roll
231150473XX	Id loops maxi red 50m dram
231151280XX	Id loops maxi red 18" steriile
231220371XX	Id loops super maxi yellow 50m roll
231220473XX	Id loops super maxi yellow 50m dram

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231221280XX	**Id loops super maxi yellow 18" sterile**
231230371XX	**Id loops super maxi blue 50m roll**
231230473XX	**Id loops super maxi blue 50m dram**
231231280XX	**Id loops super maxi blue 18" sterile**
231240371XX	**Id loops super maxi white 50m roll**
231240473XX	**Id loops super maxi white 50m dram**
231241280XX	**Id loops super maxi white 18" sterile**
231250371XX	**Id loops super maxi red 50m roll**
231250473XX	**Id loops super maxi red 50m dram**
231251280XX	**Id loops super maxi red 18" sterile**

Declaration of Conformity (DOC) Corrigendum

Product name: Identi Loops

REF: MDCG - 2020-3_guidance_significant_changes and NBOG_BPG_2014_3 (002)

Class: IIa, Rule 7

A correction of the information in previous DOC is necessary to clarify that Customer Part Number is equivalent to Degania part number, and both indicate for the same device.

customer model number	Degania model number	Description
VLMAXB	231131280MY	Id-Loops Maxi Blue 18" Sterile
VLMAXR	231151280MY	Id-Loops Maxi Red 18" Sterile
VLMAXW	231141280MY	Id-Loops Maxi White 18" Sterile
VLMAXY	231121280MY	Id-Loops Maxi Yellow 18" Sterile
VLMINB	231031280MY	Id-Loops Mini Blue 18" Sterile
VLMINR	231051280MY	Id-Loops Mini Red 18" Sterile
VLMINW	231041280MY	Id-Loops Mini White 18" Sterile
VLMINY	231021280MY	Id-Loops Mini Yellow 18" Sterile
VLSMAXB	231231280MY	Id-Loops Super Maxi Blue 18" Sterile

According to Regulation (EU) 2017/745 (MDR), for legacy devices according to Art. 120 (3), no changes to DOCs signed prior to May 26, 2021, can be performed. In case of the above described non-significant change(s) (as defined in MDCG 2020-3), the existing DOC(s) are still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to MDR.

Degania Silicone Israel
Place

08/09/24
Date

Legally Binding Signature

Tal Gafni, RA team leader
Name and Function