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: Feeding Tubes and accessories

Products sub-groups: Gastrostomy Tubes and Jejunal Tubes

Classification:Class IIb, Rule 5

Intended Use:Intended for the administration of nutrition, fluids and/or medications via well-established stoma of the patients

GMDN Code: 35419

CND Code: G02020201

Applicable Standards: 11-005 REV01 list of standards TF 3.02

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

Appendix A - List of devices:

Reference #	Description
103005001280XX	G.Tube 12Fr 3-Way White Sterile
103005001480XX	G.Tube 14Fr 3-Way White Sterile
103005001680XX	G.Tube 16Fr 3-Way White Sterile
103005001880XX	G.Tube 18Fr 3-Way White Sterile
103005002080XX	G.Tube 20Fr 3-Way White Sterile
103005002280XX	G.Tube 22Fr 3-Way White Sterile
103005002480XX	G.Tube 24Fr 3-Way White Sterile
103007001280XX	G.Tube 12Fr 3-Way 5ml Natural Sterile
103007001480XX	G.Tube 14Fr 3-Way 5ml Natural Sterile
103007001680XX	G.Tube 16Fr 3-Way 10ml Natural Sterile
103007001880XX	G.Tube 18Fr 3-Way 15ml Natural Srerile
103007002080XX	G.Tube 20Fr 3-Way 15ml Natural Sterile
103007002280XX	G.Tube 22Fr 3-Way 15ml Natural Sterile
103007002480XX	G.Tube 24Fr 3-Way 15ml Natural Sterile
103014001280XX	G.Tube 12Fr 2-Way 5ml Natural Sterile
103014001480XX	G.Tube 14Fr 2-Way 5ml Natural Sterile
103014001680XX	G.Tube 16Fr 2-Way 10ml Natural Sterile
103014001880XX	G.Tube 18Fr 2-Way 15ml Natural Sterile
103014002080XX	G.Tube 20Fr 2-Way 15ml Natural Sterile
103073002263XX	G-Tube with ENFit 1-WAY 22FR Non Sterile
103073002463XX	G-Tube with ENFit 1-WAY 24FR Non Sterile
103073031480XX	G-Tube with ENFit,ERD,Clamp 1-WAY 14FR Sterile
103073031680XX	G-Tube with ENFit,ERD,Clamp 1-WAY 16FR Sterile
103073031880XX	G-Tube with ENFit,ERD,Clamp 1-WAY 18FR Sterile
103073032080XX	G-Tube with ENFit,ERD,Clamp 1-WAY 20FR Sterile
103073032280XX	G-Tube with ENFit,ERD,Clamp 1-WAY 22FR Sterile
103073032480XX	G-Tube with ENFit,ERD,Clamp 1-WAY 24FR Sterile
103075001263XX	G-Tube with ENFit 3-WAY 12FR Non Sterile
103075031480XX	G-Tube with ENFit,ERD,Clamp 3-WAY 14FR Sterile
103075031880XX	G-Tube with ENFit,ERD,Clamp 3-WAY 18FR Sterile
103075032280XX	G-Tube with ENFit,ERD,Clamp 3-WAY 22FR Sterile
103075032480XX	G-Tube with ENFit,ERD,Clamp 3-WAY 24FR Sterile
103073001463XX	G-Tube with ENFit 1-WAY 14FR Non Sterile

103073001863XX	G-Tube with ENFit 1-WAY 18FR Non Sterile
103075001280XX	G-Tube with ENFit 3-WAY 12FR Sterile
103075001463XX	G-Tube with ENFit 3-WAY 14FR Non Sterile
103075001863XX	G-Tube with ENFit 3-WAY 18FR Non Sterile
103081001880XX	G-Tube NON ENFit 3-WAY 18FR Sterile
103081002280XX	G-Tube NON ENFit 3-WAY 22FR Sterile
103075002263XX	G-Tube with ENFit 3-WAY 22FR Non Sterile
103075002280XX	G-Tube with ENFit 3-WAY 22FR Sterile
103075031280XX	G-Tube with ENFit,ERD,Clamp 3-WAY 12FR Sterile
103075002463XX	G-Tube with ENFit 3-WAY 24FR Non Sterile
103075031680XX	G-Tube with ENFit,ERD,Clamp 3-WAY 16FR Sterile
103075032080XX	G-Tube with ENFit,ERD,Clamp 3-WAY 20FR Sterile
103081001280XX	G-Tube NON ENFit 3-WAY 12FR Sterile
103081001480XX	G-Tube NON ENFit 3-WAY 14FR Sterile
103081001680XX	G-Tube NON ENFit 3-WAY 16FR Sterile
103073001263XX	G-Tube with ENFit 1-WAY 12FR Non Sterile
103073031280XX	G-Tube with ENFit,ERD,Clamp 1-WAY 12FR Sterile
103075001680XX	G-Tube with ENFit 3-WAY 16FR Sterile
103075001880XX	G-Tube with ENFit 3-WAY 18FR Sterile
103075002063XX	G-Tube with ENFit 3-WAY 20FR Non Sterile
103075002080XX	G-Tube with ENFit 3-WAY 20FR Sterile
103075002480XX	G-Tube with ENFit 3-WAY 24FR Sterile
103073001663XX	G-Tube with ENFit 1-WAY 16FR Non Sterile
103073002063XX	G-Tube with ENFit 1-WAY 20FR Non Sterile
103075001480XX	G-Tube with ENFit 3-WAY 14FR Sterile
103075001663XX	G-Tube with ENFit 3-WAY 16FR Non Sterile
103081002080XX	G-Tube NON ENFit 3-WAY 20FR Sterile

103081002480XX	G-Tube NON ENFit 3-WAY 24FR Sterile
103014002280XX	G.Tube 22Fr 2-Way 15ml Natural Sterile
103014002480XX	G.Tube 24Fr 2-Way 15ml Natural Sterile
103015001080XX	G.Tube 10Fr 2-Way 3ml Natural Sterile
103015001480XX	G.Tube 14Fr 2-Way 5ml Natural Sterile
103015001680XX	G.Tube 16Fr 2-Way 10ml Natural Sterile
103015001880XX	G.Tube 18Fr 2-Way 15ml Natural Sterile
103015002080XX	G.Tube 20Fr 2-Way 15ml Natural Sterile
103058001280XX	Jejunal Tube 12Fr 2-Way Sterile
103058001480XX	Jejunal Tube 14Fr 2-Way Sterile
103058001680XX	Jejunal Tube 16Fr 2-Way Sterile
103058001880XX	Jejunal Tube 18Fr 2-Way Sterile
103058002080XX	Jejunal Tube 20Fr 2-Way Sterile
103058002280XX	Jejunal Tube 22Fr 2-Way Sterile
103058002480XX	Jejunal Tube 24Fr 2-Way Sterile
103059001080XX	Jejunal Tube 10Fr 3-Way Sterile
103059001280XX	Jejunal Tube 12Fr 3-Way Sterile
103059001480XX	Jejunal Tube 14Fr 3-Way Sterile
103059001680XX	Jejunal Tube 16Fr 3-Way Sterile
103059001880XX	Jejunal Tube 18Fr 3-Way Sterile
103059002080XX	Jejunal Tube 20Fr 3-Way Sterile
103059002280XX	Jejunal Tube 22Fr 3-Way Sterile
103059002480XX	Jejunal Tube 24Fr 3-Way Sterile
103080002480XX	Jejunal Tube with ENFit 1-Way 24Fr Sterile
103080001680XX	Jejunal Tube with ENFit 1-Way 16Fr Sterile
103080002080XX	Jejunal Tube with ENFit 1-Way 20Fr Sterile
103080001280XX	Jejunal Tube with ENFit 1-Way 12Fr Sterile
103080001480XX	Jejunal Tube with ENFit 1-Way 14Fr Sterile
103080001210XX	Jejunal Tube with ENFit 1-Way 12Fr In Process
103080001880XX	Jejunal Tube with ENFit 1-Way 18Fr Sterile
103080002280XX	Jejunal Tube with ENFit 1-Way 22Fr Sterile
103060001080XX	2-WAY GASTROSTOMY TUBE 10FR 3CC Sterile
103060001280XX	2-WAY GASTROSTOMY TUBE 12FR 5CC Sterile
103060001480XX	2-WAY GASTROSTOMY TUBE 14FR 5CC Sterile
103060001680XX	2-WAY GASTROSTOMY TUBE 16FR 10CC Sterile
103060001880XX	2-WAY GASTROSTOMY TUBE 18FR 15CC Sterile
103060002080XX	2-WAY GASTROSTOMY TUBE 20FR 15CC Sterile
103060002280XX	2-WAY GASTROSTOMY TUBE 22FR 15CC Sterile

103060002480XX	2-WAY GASTROSTOMY TUBE 24FR 15CC Sterile
103061001080XX	2-WAY GASTROSTOMY TUBE 10FR 3CC Sterile
103061001280XX	2-WAY GASTROSTOMY TUBE 12FR 3CC Sterile
103061001480XX	2-WAY GASTROSTOMY TUBE 14FR 4CC Sterile
103061001680XX	2-WAY GASTROSTOMY TUBE 16FR 5CC Sterile
103061001880XX	2-WAY GASTROSTOMY TUBE 18FR 5CC Sterile
103061002080XX	2-WAY GASTROSTOMY TUBE 20FR 8CC Sterile
103061002280XX	2-WAY GASTROSTOMY TUBE 22FR 8CC Sterile
103061002480XX	2-WAY GASTROSTOMY TUBE 24FR 8CC Sterile
103063001280XX	2Way G-Tube with Y ENFit 12FR Sterile
103063001480XX	2Way G-Tube with Y ENFit 14FR Sterile
103063001680XX	2Way G-Tube with Y ENFit 16FR Sterile
103063001880XX	2Way G-Tube with Y ENFit 18FR Sterile
103063002080XX	2Way G-Tube with Y ENFit 20FR Sterile
103063002280XX	2Way G-Tube with Y ENFit 22FR Sterile
103063002480XX	2Way G-Tube with Y ENFit 24FR Sterile
103069001280XX	3-WAY GASTROSTOMY TUBE 12FR Sterile
103069001480XX	3-WAY GASTROSTOMY TUBE 14FR Sterile
103069001680XX	3-WAY GASTROSTOMY TUBE 16FR Sterile
103069001880XX	3-WAY GASTROSTOMY TUBE 18FR Sterile
103069002080XX	3-WAY GASTROSTOMY TUBE 20FR Sterile
103069002280XX	3-WAY GASTROSTOMY TUBE 22FR Sterile
103069002480XX	3-WAY GASTROSTOMY TUBE 24FR Sterile
103070001280XX	G-Tube with ENFit 1-WAY 12FR Sterile
103070001480XX	G-Tube with ENFit 1-WAY 14FR Sterile
103070001680XX	G-Tube with ENFit 1-WAY 16FR Sterile
103070001880XX	G-Tube with ENFit 1-WAY 18FR Sterile
103070002080XX	G-Tube with ENFit 1-WAY 20FR Sterile
103070002280XX	G-Tube with ENFit 1-WAY 22FR Sterile
103070002480XX	G-Tube with ENFit 1-WAY 24FR Sterile
103071001280XX	G-Tube with ENFit 3-WAY 12FR Sterile
103071001480XX	G-Tube with ENFit 3-WAY 14FR Sterile
103071001680XX	G-Tube with ENFit 3-WAY 16FR Sterile
103071001880XX	G-Tube with ENFit 3-WAY 18FR Sterile
103071002080XX	G-Tube with ENFit 3-WAY 20FR Sterile
103071002280XX	G-Tube with ENFit 3-WAY 22FR Sterile
103071002480XX	G-Tube with ENFit 3-WAY 24FR Sterile
103072001080XX	G.Tube 10Fr 2-Way funnel with ENFit Sterile
103072001480XX	G.Tube 14Fr 2-Way funnel with ENFit Sterile
103072001680XX	G.Tube 16Fr 2-Way funnel with ENFit Sterile
103072001880XX	G.Tube 18Fr 2-Way funnel with ENFit Sterile
103072002080XX	G.Tube 20Fr 2-Way funnel with ENFit Sterile
103073001280XX	G-Tube with ENFit 1-WAY 12FR Sterile

103073001480XX	G-Tube with ENFit 1-WAY 14FR Sterile
103073001680XX	G-Tube with ENFit 1-WAY 16FR Sterile
103073001880XX	G-Tube with ENFit 1-WAY 18FR Sterile
103073002080XX	G-Tube with ENFit 1-WAY 20FR Sterile
103073002280XX	G-Tube with ENFit 1-WAY 22FR Sterile
103073002480XX	G-Tube with ENFit 1-WAY 24FR Sterile
103074001280XX	G-Tube with ENFit 2-WAY 12FR Sterile
103074001480XX	G-Tube with ENFit 2-WAY 14FR Sterile
103074001680XX	G-Tube with ENFit 2-WAY 16FR Sterile
103074001880XX	G-Tube with ENFit 2-WAY 18FR Sterile
103074002080XX	G-Tube with ENFit 2-WAY 20FR Sterile
103074002280XX	G-Tube with ENFit 2-WAY 22FR Sterile
103074002480XX	G-Tube with ENFit 2-WAY 24FR Sterile
103078011080XX	G.Tube 10Fr 2W ENFit-crimped ring-Sterile
103078011280XX	G.Tube 12Fr 2W ENFit-crimped ring-Sterile
103078011480XX	G.Tube 14Fr 2W ENFit-crimped ring-Sterile
103078011680XX	G.Tube 16Fr 2W ENFit-crimped ring-Sterile
103078011880XX	G.Tube 18Fr 2W ENFit-crimped ring-Sterile
103078012080XX	G.Tube 20Fr 2W ENFit-crimped ring-Sterile
103078012280XX	G.Tube 22Fr 2W ENFit-crimped ring-Sterile
103078012480XX	G.Tube 24Fr 2W ENFit-crimped ring-Sterile

Date: 07 April 2022

To whom it may concern,

Declaration

Hereby to confirm that,

The products listed in table 1 are included in the DoC signed on the 28-Mar-2022, 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.

Nutricia Product code	**Degania product code**
178129	103082011080NT
178130	103082011280NT
178131	103082011480NT
178132	103082011680NT
178133	103082011880NT
178134	103082012080NT

Degania Signature:

Tali Raz

QA&RA Director Endosurgery

Declaration of Conformity (DOC) Corrigendum

Revision Control:

Rev №	Valid from date	Description of change
01	23/08/2022	Addition of CH-REP details to DOC(s).
02	13/09/2022	Clarification of typo with the CH-REP and an addition of UK-REP to DOC(s). Correction of REF No. to align with the DOC(s)

Prepared by	Position	Signature	Date
Lina Godha	RA Clinical Affairs Coordinator	Lina	13/09/2022
Approved by	**Position**	**Signature**	**Date**
Tali Raz	QA/RA Director		13/09/22

Product name: Gastrostomy Button

REF: 1033*80XX

Class: IIb

Date of the DOC: 28-Mar-2022

Product name: Gastrostomy Tubes and Jejunal Tubes

REF: 1030*80XX,10305*80XX

Class: IIb

Date of the DOC: 28-Mar-2022

Product name: Nasogastric Tube, and Nasojejunal Tube

REF: 1660*80XX

Class: IIb

Date of the DOC: 28-Mar-2022

Product name: Silicone Tubing

REF: 2320*80XX

Class: IIa

Date of the DOC: 28-Mar-2022

Product name: Identi loops

REF: 231*80XX

Class: IIa

Date of the DOC: 28-Mar-2022

Product name: Silclamps

REF: 2320*80XX

Class: IIa

Date of the DOC: 28-Mar-2022

Product name: 2-way Foley catheter- Nelaton and Tieman

REF: Nelaton: 10110*80XX, Tieman: 1013*80XX

Class: IIb

Date of the DOC: 28-Mar-2022

Product name: 3-way Foley catheter

REF: 1021*80XX

Class: IIa

Date of the DOC: 28-Mar-2022

Product name: Suprapubic Catheter

REF: 1010*80XX

Class: IIb

Date of the DOC: 28-Mar-2022

Product name: TSC catheter

REF: 1022*80XX

Class: IIb

Date of the DOC: 28-Mar-2022

Product name: Multilumen and Easy flow

REF: 1120*80XX

Class: IIa

Date of the DOC: 28-Mar-2022

Product name: Flat perforated drain, Round perforated drain, Fluted Round & Flat drain

REF: 1110*80XX ,11003*80XX, 11000*80XX, 11101*80XX

Class: IIa

Date of the DOC:05-APR-2022

This corrigendum intends to add the following information in the DoC(s) of the above listed product(s).

The Name and address of CH-REP:

MedNet SWISS GmbH,

Bäderstrasse 18,

5400 Baden,

Switzerland

The Name and address of UK-REP:

MediMap Ltd,

2 The Drift,

Thurston,

Suffolk, IP31 3RT

United Kingdom

Name and address of the EC-REP and Importer will remain:

Biometrix SRO

Vicenzy 16S

Samorin, 93101

Slovakia

SRN: SK-AR-000002253

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.

Israel, 13/09/22

Place/Date

legally binding signature

Tali Raz

Name and function