

DECLARATION OF CONFORMITY TO THE MEDICAL DEVICE DIRECTIVE

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

Manufacturer Name and Address:

Degania Silicone Ltd
Degania bet, 1513000
Israel

Notified body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 MÜNCHEN
Germany

European representative:

Biometrix SRO
Vicenzy 16S
Samorin , 93101
Slovakia

Product family: Feeding Tubes and accessories

Products sub-groups: Gastrostomy Button

Class: IIb, Rule 5

GMDN code: 38565

Certificate No: G1 041538 0005

Herewith to declare that:

Hereby to declare that the above mentioned product comply with Annex II 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



Elian Ben Graff, RA Manager

March 11, 2020

Date

Annex A:

Nutricia Ref#	Degania Ref#	Description
152911	103302011282NT	BUTTON SET CH 12 / 0.8 CM ENFIT
152913	103302021282NT	BUTTON SET CH 12 / 1.0 CM ENFIT
152983	103302031282NT	BUTTON SET CH 12 / 1.2 CM ENFIT
152982	103302041282NT	BUTTON SET CH 12 / 1.5 CM ENFIT
152981	103302051282NT	BUTTON SET CH 12 / 1.7 CM ENFIT
152980	103302061282NT	BUTTON SET CH 12 / 2.0 CM ENFIT
152979	103302071282NT	BUTTON SET CH 12 / 2.3 CM ENFIT
152978	103302081282NT	BUTTON SET CH 12 / 2.5 CM ENFIT
153000	103302101282NT	BUTTON SET CH 12 / 3.0 CM ENFIT
152999	103302111282NT	BUTTON SET CH 12 / 3.5 CM ENFIT
152998	103302121282NT	BUTTON SET CH 12 / 4.0 CM ENFIT
152997	103302141282NT	BUTTON SET CH 12 / 5.0 CM ENFIT
152996	103302011482NT	BUTTON SET CH 14 / 0.8 CM ENFIT
152995	103302021482NT	BUTTON SET CH 14 / 1.0CM ENFIT
152994	103302031482NT	BUTTON SET CH 14 / 1.2 CM ENFIT
152993	103302041482NT	BUTTON SET CH 14 / 1.5CM ENFIT
152992	103302051482NT	BUTTON SET CH 14 / 1.7 CM ENFIT
152991	103302061482NT	BUTTON SET CH 14 / 2.0CM ENFIT
152990	103302071482NT	BUTTON SET CH 14 / 2.3CM ENFIT
152989	103302081482NT	BUTTON SET CH 14 / 2.SCM ENFIT
152988	103302091482NT	BUTTON SET CH 14 / 2.7 CM ENFIT
152987	103302101482NT	BUTTON SET CH 14 / 3.0CM ENFIT

152986	103302111482NT	BUTTON SET CH 14 / 3.SCM ENFIT
152985	103302121482NT	BUTTON SET CH 14 / 4.0CM ENFIT
152984	103302131482NT	BUTTON SET CH 14 / 4.5 CM ENFIT
153048	103302141482NT	BUTTON SET CH 14 / 5.0 CM ENFIT
153047	103302011682NT	BUTTON SET CH 16 / 0.8 CM ENFIT
153046	103302021682NT	BUTTON SET CH 16 / 1.0 CM ENFIT
153045	103302031682NT	BUTTON SET CH 16 / 1.2 CM ENFIT
153044	103302041682NT	BUTTON SET CH 16 / 1.5 CM ENFIT
153043	103302051682NT	BUTTON SET CH 16 / 1.7 CM ENFIT
153042	103302061682NT	BUTTON SET CH 16 / 2.0 CM ENFIT
153041	103302071682NT	BUTTON SET CH 16 / 2.3 CM ENFIT
153040	103302081682NT	BUTTON SET CH 16 / 2.5 CM ENFIT
153039	103302091682NT	BUTTON SET CH 16 / 2.7 CM ENFIT
153038	103302101682NT	BUTTON SET CH 16 / 3.0 CM ENFIT
153037	103302111682NT	BUTTON SET CH 16 / 3.5 CM ENFIT
153036	103302121682NT	BUTTON SET CH 16 / 4.0 CM ENFIT
153035	103302131682NT	BUTTON SET CH 16 / 4.5 CM ENFIT
153034	103302011882NT	BUTTON SET CH 18 / 0.8 CM ENFIT
153033	103302021882NT	BUTTON SET CH 18 / 1.0CM ENFIT
153032	103302031882NT	BUTTON SET CH 18 / 1.2 CM ENFIT
153089	103302041882NT	BUTTON SET CH 18 / 1.5CM ENFIT
153088	103302051882NT	BUTTON SET CH 18 / 1.7 CM ENFIT
153087	103302061882NT	BUTTON SET CH 18 / 2.0CM ENFIT
153086	103302071882NT	BUTTON SET CH 18 / 2.3CM ENFIT
153085	103302081882NT	BUTTON SET CH 18 / 2.SCM ENFIT
153084	103302091882NT	BUTTON SET CH 18 / 2.7 CM ENFIT
153083	103302101882NT	BUTTON SET CH 18 / 3.0CM ENFIT

153082	103302111882NT	BUTTON SET CH 18 / 3.5CM ENFIT
153081	103302121882NT	BUTTON SET CH 18 / 4.0 CM ENFIT
153080	103302131882NT	BUTTON SET CH 18 / 4.5 CM ENFIT
153079	103302012082NT	BUTTON SET CH 20 / 0.8 CM ENFIT
153078	103302032082NT	BUTTON SET CH 20 / 1.2 CM ENFIT
153077	103302042082NT	BUTTON SET CH 20 / 1.5 CM ENFIT
153076	103302052082NT	BUTTON SET CH 20 / 1.7 CM ENFIT
153075	103302062082NT	BUTTON SET CH 20 / 2.0 CM ENFIT
153074	103302072082NT	BUTTON SET CH 20 / 2.3 CM ENFIT
153073	103302082082NT	BUTTON SET CH 20 / 2.5 CM ENFIT
153100	103302102082NT	BUTTON SET CH 20 / 3.0 CM ENFIT
153099	103302112082NT	BUTTON SET CH 20 / 3.5 CM ENFIT
153080	103302132082NT	BUTTON SET CH 20 / 4.5 CM ENFIT
153097	103302062482NT	BUTTON SET CH 24 / 1.5 CM ENFIT
1 53096	103302072482NT	BUTTON SET CH 24 / 1.7 CM ENFIT
153095	103302082482NT	BUTTON SET CH 24 / 2.0 CM ENFIT
153094	103302092482NT	BUTTON SET CH 24 / 2.3 CM ENFIT
153093	103302102482NT	BUTTON SET CH 24 / 2.5 CM ENFIT
153092	103302112482NT	BUTTON SET CH 24 / 2.7 CM ENFIT
153091	103302122482NT	BUTTON SET CH 24 / 3.0 CM ENFIT
153090	103302062482NT	BUTTON SET CH 24 / 3.5 CM ENFIT
153101	103302072482NT	BUTTON SET CH 24 / 4.0 CM ENFIT
160507		Stoma Measuring Device

End of List