



DECLARATION OF CONFORMITY

To Council Directive 93/42/EEC of 14 June 1993

Manufacturer: **T.A.G. Medical Products Corporation LTD.**
Kibbutz Gaaton 2513000 Israel
Tel: (972) 4 9858400
Fax: (972) 4 9858404
E-mail: tagltd@netvision.net.il

EC Authorized Representative: **MedNet GmbH**
Borkstrasse 10
48163 Munster, Germany
Fax: +49 251 32266-22

I, the undersigned, hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number n°32655, issued on 27-FEB-2017 and delivered by LNE G-MED, Paris cedex, France, Notified Body Identification Number 0459, in accordance with Annex II of the Council Directives 93/42/EEC of 14 June 1993 concerning medical devices.

This declaration is supported by the Quality System certificate for the products concerned, in accordance with Annex II of the EC-Directive. The conformity to quality assurance set out in the said ISO 13485:2003, EN ISO 13485:2012 Conformity Certificate numbers; n°32659 and n°32657, issued and delivered by LNE G-MED, Paris cedex, France.

Issue place and date: Gaaton, 17-JUN-2017

Signature:

Name:

Hagay Sitry

Position

CEO

This certificate is valid until: July 1, 2018



DECLARATION OF CONFORMITY ANNEX 1 - PRODUCT LIST

This product list below belongs to the Declaration of Conformity identified by T.A.G. Medical Products Corporation LTD. and specifies the CE marked products that T.A.G. Medical Products Corporation LTD. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Product Dental Implants
GMDN 55847 Dental Implant System
Classification Class IIb, Rule 8
Placed in the market November 2012

Part Number	Description
IM1-37508	Massif Implant ø3.75 L8mm
IM1-37510	Massif Implant ø3.75 L10mm
IM1-37511	Massif Implant ø3.75 L11.50mm
IM1-37513	Massif Implant ø3.75 L13mm
IM1-37516	Massif Implant ø3.75 L16mm
IM1-42006	Massif Implant ø4.20 L6mm
IM1-42008	Massif Implant ø4.20 L8mm
IM1-42010	Massif Implant ø4.20 L10mm
IM1-42011	Massif Implant ø4.20 L11.50mm
IM1-42013	Massif Implant ø4.20 L13mm
IM1-42016	Massif Implant ø4.20 L16mm
IM1-50006	Massif Implant ø5 L6mm
IM1-50008	Massif Implant ø5 L8mm
IM1-50010	Massif Implant ø5 L10mm
IM1-50011	Massif Implant ø5 L11.50mm
IM1-50013	Massif Implant ø5 L13mm
IM1-60006	Massif Implant ø6 L6mm
IM1-60008	Massif Implant ø6 L8mm
IM1-60010	Massif Implant ø6 L10mm



MEDICAL PRODUCTS

Part Number	Description
IM1-60011	Massif Implant ø6 L11.50mm
IM1-60013	Massif Implant ø6 L13mm
IA1-33008	Axis Implant ø3.30 L8mm
IA1-33010	Axis Implant ø3.30 L10mm
IA1-33011	Axis Implant ø3.30 L11.50mm
IA1-33013	Axis Implant ø3.30 L13mm
IA1-33016	Axis Implant ø3.30 L16mm
IA1-37508	Axis Implant ø3.75 L8mm
IA1-37510	Axis Implant ø3.75 L10mm
IA1-37511	Axis Implant ø3.75 L11.50mm
IA1-37513	Axis Implant ø3.75 L13mm
IA1-37516	Axis Implant ø3.75 L16mm
IA1-42006	Axis Implant ø4.20 L6mm
IA1-42008	Axis Implant ø4.20 L8mm
IA1-42010	Axis Implant ø4.20 L10mm
IA1-42011	Axis Implant ø4.20 L11.50mm
IA1-42013	Axis Implant ø4.20 L13mm
IA1-42016	Axis Implant ø4.20 L16mm
IA1-50006	Axis Implant ø5 L6mm
IA1-50008	Axis Implant ø5 L8mm
IA1-50010	Axis Implant ø5 L10mm
IA1-50011	Axis Implant ø5 L11.50mm
IA1-50013	Axis Implant ø5 L13mm
IA1-60006	Axis Implant ø6 L6mm
IA1-60008	Axis Implant ø6 L8mm
IA1-60010	Axis Implant ø6 L10mm
IA1-60011	Axis Implant ø6 L11.50mm
IA1-60013	Axis Implant ø6 L13mm
IC1-30010	Crestone One Piece Implant ø3 L10mm
IC1-30011	Crestone One Piece Implant ø3 L11.50mm
IC1-30013	Crestone One Piece Implant ø3 L13mm
IC1-30016	Crestone One Piece Implant ø3 L16mm
IC1-35010	Crestone One Piece Implant ø3.50 L10mm
IC1-35011	Crestone One Piece Implant ø3.50 L11.50mm



MEDICAL PRODUCTS

Part Number	Description
IC1-35013	Crestone One Piece Implant ø3.50 L13mm
IC1-35016	Crestone One Piece Implant ø3.50 L16mm

Product Dental Implant- Cover Screws and Healing Caps
 GMDN 55847 Dental Implant System
Classification Class IIb, Rule 8
Placed in the market November 2012

Part Number	Description
PH1-0001	Cover screw
PH1-0016	Healing cap 2mm
PH1-0002	Healing Cap 3mm
PH1-0003	Healing Cap 4mm
PH1-0004	Healing Cap 5mm
PH1-0005	Healing Cap 6mm
PH1-0017	Anatomic Healing cap 2mm
PH1-0006	Anatomic Healing cap 3mm
PH1-0007	Anatomic Healing cap 4mm
PH1-0008	Anatomic Healing cap 5mm
PH1-0009	Anatomic Healing cap 6mm
PH1-0018	Anatomic Healing Cap 2mm Wide
PH1-0013	Anatomic Healing Cap 3mm Wide
PH1-0014	Anatomic Healing Cap 4mm Wide
PH1-0015	Anatomic Healing Cap 5mm Wide
PH1-0019	Anatomic Healing Cap 6mm Wide
PF1-0017	Healing Cap Plastic 4mm
PF1-0018	Healing Cap Plastic 6mm
PF1-0019	Healing Cap Plastic 8mm
PO1-0024	Multi-Unit Healing Cap
PH1-0021	ARK Healing Cap PEEK 4mm
PH1-0022	ARK Healing Cap PEEK 6mm
PH1-0023	ARK Healing Cap PEEK 8mm



Product Dental Implant - Superstructure Components
Classification GMDN 55847 Dental Implant System
Placed in the market Class IIb, Rule 8
 November 2012

Part Number	Description
PT1-0001	Temporary Abutment H1mm PEEK
PT1-0003	Temporary Abutment H2mm PEEK
PT1-0004	Temporary Abutment H3mm PEEK
PT1-0005	15° Temporary Abutment H1mm PEEK
PT1-0006	15° Temporary Abutment H2mm PEEK
PT1-0007	15° Temporary Abutment H3mm PEEK
PT1-0008	25° Temporary Abutment H1mm PEEK
PT1-0009	25° Temporary Abutment H2mm PEEK
PT1-0010	25° Temporary Abutment H3mm PEEK
PF1-0001	Titanium Abutment Screw
PF1-0002	Shouldered Abutment Screw
PF1-0004	Gold screw for Internal hex. Abutment
PF1-0005	Anatomic Abutment H1mm L4mm
PF1-0006	Anatomic Abutment H1mm L6mm
PF1-0007	Anatomic Abutment H1mm L8mm
PF1-0008	Anatomic Abutment H2mm L4mm
PF1-0009	Anatomic Abutment H2mm L6mm
PF1-0010	Anatomic Abutment H2mm L8mm
PF1-0011	Anatomic Abutment H3mm L4mm
PF1-0012	Anatomic Abutment H3mm L6mm
PF1-0013	Anatomic Abutment H3mm L8mm
PF1-0014	Anatomic Abutment H4mm L4mm
PF1-0015	Anatomic Abutment H4mm L6mm



MEDICAL PRODUCTS

Part Number	Description
PF1-0016	Anatomic Abutment H4mm L8mm
PF1-0065	Anatomic Abutment H2mm L6mm Wide
PF1-0064	Anatomic Abutment H3mm L6mm Wide
PF1-0063	Anatomic Abutment H4mm L6mm Wide
PF1-0020	Burn-out Anti-rotation Cap
PF1-0021	Burn-out Round Cap
PF1-0023	Titanium Universal Abutment H2mm
PF1-0081	Universal Abutment H0mm
PF1-0068	Titanium Universal Abutment Wide H2mm
PF1-0026	Esthetic Abutment H1mm Ti
PF1-0027	Esthetic Abutment H2mm Ti
PF1-0028	Esthetic Abutment H3mm Ti
PF1-0029	15° Esthetic Abutment H1mm Ti
PF1-0030	15° Esthetic Abutment H2mm Ti
PF1-0031	15° Esthetic Abutment H3mm Ti
PF1-0032	25° Esthetic Abutment H1mm Ti
PF1-0033	25° Esthetic Abutment H2mm Ti
PF1-0034	25° Esthetic Abutment H3mm Ti
PF1-0037	Esthetic Abutment H1mm Burn-Out
PF1-0039	Esthetic Abutment H2mm Burn-Out
PF1-0040	Esthetic Abutment H3mm Burn-Out
PF1-0041	15° Esthetic Abutment H1mm Burn-Out
PF1-0042	15° Esthetic Abutment H2mm Burn-Out
PF1-0043	15° Esthetic Abutment H3mm Burn-Out
PF1-0044	25° Esthetic Abutment H1mm Burn-Out
PF1-0045	25° Esthetic Abutment H2mm Burn-Out
PF1-0046	25° Esthetic Abutment H3mm Burn-Out
PF1-0038	Esthetic Abutment Burn-Out Round
PF1-0024	15° Angulated Abutment



MEDICAL PRODUCTS

Part Number	Description
PF1-0025	25° Angulated Abutment
PF1-0066	15° Angulated Abutment H2mm Ti Wide
PF1-0067	25° Angulated Abutment H2mm Ti Wide
PF1-0069	Narrow Abutment H0mm
PF1-0077	Narrow Abutment H0mm
PF1-0073	Narrow Abutment H0mm
PF1-0082	Narrow Solid Abutment H0mm
PF1-0035	Direct Plastic Cylinder With Hex.
PF1-0036	Direct Plastic Cylinder Round
PF1-0058	Plastic Cylinder with Hex Ti
PF1-0057	Plastic Cylinder with Round Ti
PF1-0059	Direct gold plastic abutment cylinder with hex.
PF1-0060	Direct gold plastic abutment cylinder Round
PO1-0001	Ball Attachment 1 mm
PO1-0002	Ball Attachment 2 mm
PO1-0003	Ball Attachment 3 mm
PO1-0004	Ball Attachment 4 mm
PO1-0005	Ball Attachment 5 mm
PO1-0042	Ball Attachment 17° 2mm
PO1-0043	Ball Attachment 17° 3mm
PO1-0044	Ball Attachment 30° 2mm
PO1-0045	Ball Attachment 30° 3mm
PO1-0046	Ti Screw for M.U. & Balls
PO1-0009	Metal Housing for Plastic Ball Cap
PO1-0010	Plastic Ball Attachment Cap
PO1-0011	Extra Soft Plastic Cap Ball



MEDICAL PRODUCTS

Part Number	Description
PO1-0012	Soft Plastic Cap Ball
PO1-0013	Standard Plastic Cap Ball
PO1-0014	Plastic Disc for Ball Attachment
PO1-0016	Multi-Unit H1mm
PO1-0017	Multi-Unit H2mm
PO1-0018	Multi-Unit H3mm
PO1-0019	Multi-Unit H4mm
PO1-0020	Multi-Unit H5mm
PO1-0038	Multi-Unit 17° 2mm
PO1-0039	Multi-Unit 17° 3mm
PO1-0040	Multi-Unit 30° 2mm
PO1-0041	Multi-Unit 30° 3mm
PO1-0025	Multi-Unit Ti Screw
PO1-0026	Multi-Unit Gold Screw
PO1-0027	Multi-Unit Plastic Cylinder
PO1-0028	Multi-Unit Temporary Ti
PO1-0029	Multi-Unit Temporary PEEK
PO1-0030	Multi-Unit Direct Gold
CCK-0001	CAD/CAM Abutment Kit Narrow
CCA-0001	CAD/CAM Base Narrow
CCK-0002	CAD/CAM Abutment Kit Narrow Round
CCA-0002	CAD/CAM Base Narrow Round
PO1-0055	Equator Attachment H0mm
PO1-0056	Equator Attachment H1mm
PO1-0057	Equator Attachment H2mm
PO1-0058	Equator Attachment H3mm
PO1-0059	Equator Attachment H4mm
PO1-0060	Equator Attachment H5mm
PO1-0062	Equator Attachment Metal Housing



MEDICAL PRODUCTS

Part Number	Description
PO1-0063	Equator Attachment Cap Standard Clear
PO1-0064	Equator Attachment Cap Soft Pink
PO1-0065	Equator Attachment Laboratory Cap Black
PO1-0066	Equator Attachment Cap Extra Soft Yellow
PO1-0067	Equator Attachment Cap Strong Violet
PF1-ARK14	Anatomic Restoration Kit H1mm L4mm
PF1-ARK16	Anatomic Restoration Kit H1mm L6mm
PF1-ARK18	Anatomic Restoration Kit H1mm L8mm
PF1-ARK24	Anatomic Restoration Kit H2mm L4mm
PF1-ARK26	Anatomic Restoration Kit H2mm L6mm
PF1-ARK28	Anatomic Restoration Kit H2mm L8mm
PF1-ARK34	Anatomic Restoration Kit H3mm L4mm
PF1-ARK36	Anatomic Restoration Kit H3mm L6mm
PF1-ARK38	Anatomic Restoration Kit H3mm L8mm
PF1-ARK44	Anatomic Restoration Kit H4mm L4mm
PF1-ARK46	Anatomic Restoration Kit H4mm L6mm
PF1-ARK48	Anatomic Restoration Kit H4mm L8mm
PO1-0070	Equator Abutment H0mm
PO1-0071	Equator Abutment H1mm
PO1-0072	Equator Abutment H2mm
PO1-0073	Equator Abutment H3mm
PO1-0074	Equator Abutment H4mm
PO1-0075	Equator Abutment H5mm
CCK-0004	CAD/CAM Multi Unit Abutment Kit
CCA-0011	CAD/CAM Blank \varnothing 9
CCA-0012	CAD/CAM Blank \varnothing 12
CCA-0013	CAD/CAM Blank for Multi Unit
PO1-0047	Multi-Unit 17° 4mm
PO1-0049	Multi-Unit 30° 4mm



MEDICAL PRODUCTS

Part Number	Description
PO1-0051	Ball Attachment 17° 4mm
PO1-0053	Ball Attachment 30° 4mm