

EC DECLARATION OF CONFORMITY

We: "MIS Implants Technologies Ltd."

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Declare under our sole responsibility that the products:

Dental Drills – CG, MG, MO, MT& MK (See attached list of products)

meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them.

The product(s) is (are) intended to be used by licensed dentist, for treatment of patient in the clinic.

The product(s) is (are) intended to provide a variety of clinical solutions, including reconstruction of single tooth, screw – retained or cemented fixed bridges and over-dentures.

The devices are classified in Class IIa according to Rule no.6 of Annex IX of the Medical Device Directive.

Conformity assessment was performed according to Annex II.3 of the Directive and applicable standards.

The authorized representative within the EU who has been empowered to enter into commitments in our behalf:

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http://www.mdc-ce.de

This D.O.C is valid until: 16.03.2017

Date: 16.03.2015



Efrat Shamgar

QA & RA Manager

List of products

| Catalog Number | Description |
|-----------------------|--|
| CG-D0633 | MGUIDE C1 conical drill for imp. dia.3.30 L 6mm |
| CG-D0637 | MGUIDE C1 conical drill for imp. dia.3.75 L 6mm |
| CG-D0642 | MGUIDE C1 conical drill for imp. dia.4.20 L 6mm |
| CG-D0650 | MGUIDE C1 conical drill for imp. dia.5 L 6mm |
| CG-D0833 | MGUIDE C1 conical drill for imp. dia.3.30 L 8mm |
| CG-D0837 | MGUIDE C1 conical drill for imp. dia.3.75 L 8mm |
| CG-D0842 | MGUIDE C1 conical drill for imp. dia.4.20 L 8mm |
| CG-D0850 | MGUIDE C1 conical drill for imp. dia.5 L 8mm |
| CG-D1033 | MGUIDE C1 conical drill for imp. dia.3.30 L 10mm |
| CG-D1037 | MGUIDE C1 conical drill for imp. dia.3.75 L 10mm |
| CG-D1042 | MGUIDE C1 conical drill for imp. dia.4.20 L 10mm |
| CG-D1050 | MGUIDE C1 conical drill for imp. dia.5 L 10mm |
| CG-D1133 | MGUIDE C1 conical drill for imp. dia.3.30 L 11.50mm |
| CG-D1137 | MGUIDE C1 conical drill for imp. dia.3.75 L 11.50mm |
| CG-D1142 | MGUIDE C1 conical drill for imp. dia.4.20 L 11.50mm |
| CG-D1150 | MGUIDE C1 conical drill for imp. dia.5 L 11.50mm |
| CG-D1333 | MGUIDE C1 conical drill for imp. dia.3.30 L 13mm |
| CG-D1337 | MGUIDE C1 conical drill for imp. dia.3.75 L 13mm |
| CG-D1342 | MGUIDE C1 conical drill for imp. dia.4.20 L 13mm |
| CG-D1350 | MGUIDE C1 conical drill for imp. dia.5 L 13mm |
| CG-N0633 | MGUIDE C1 narrow conical drill for imp. dia.3.30 L 6mm |
| CG-N0637 | MGUIDE C1 narrow conical drill for imp. dia.3.75 L 6mm |
| CG-N0833 | MGUIDE C1 narrow conical drill for imp. dia.3.30 L 8mm |
| CG-N0837 | MGUIDE C1 narrow conical drill for imp. dia.3.75 L 8mm |
| CG-N1033 | MGUIDE C1 narrow conical drill for imp. dia.3.30 L 10mm |
| CG-N1037 | MGUIDE C1 narrow conical drill for imp. dia.3.75 L 10mm |
| CG-N1133 | MGUIDE C1 narrow conical drill for imp. dia.3.30 L 11.50mm |
| CG-N1137 | MGUIDE C1 narrow conical drill for imp. dia.3.75 L 11.50mm |
| CG-N1333 | MGUIDE C1 narrow conical drill for imp. dia.3.30 L 13mm |
| CG-N1337 | MGUIDE C1 narrow conical drill for imp. dia.3.75 L 13mm |
| MG-BM047 | MGUIDE bone mill dia.4.7mm |
| MG-BM055 | MGUIDE bone mill dia.5.5mm |
| MG-D0624 | MGUIDE pilot drill dia.2.40 L 6mm |
| MG-D0633 | MGUIDE conical drill for imp. dia.3.30 L 6mm |
| MG-D0637 | MGUIDE conical drill for imp. dia.3.75 L 6mm |
| MG-D0642 | MGUIDE conical drill for imp. dia.4.20 L 6mm |
| MG-D0650 | MGUIDE conical drill for imp. dia.5 L 6mm |
| MG-D0824 | MGUIDE pilot drill dia.2.40 L 8mm |
| MG-D0833 | MGUIDE conical drill for imp. dia.3.30 L 8mm |
| MG-D0837 | MGUIDE conical drill for imp. dia.3.75 L 8mm |
| MG-D0842 | MGUIDE conical drill for imp. dia.4.20 L 8mm |
| MG-D0850 | MGUIDE conical drill for imp. dia.5 L 8mm |
| MG-D1024 | MGUIDE pilot drill dia.2.40 L 10mm |
| MG-D1033 | MGUIDE conical drill for imp. dia.3.30 L 10mm |
| MG-D1037 | MGUIDE conical drill for imp. dia.3.75 L 10mm |
| MG-D1042 | MGUIDE conical drill for imp. dia.4.20 L 10mm |

| Catalog Number | Description |
|----------------|---|
| MG-D1050 | MGUIDE conical drill for imp. dia.5 L 10mm |
| MG-D1124 | MGUIDE pilot drill dia.2.40 L 11.50mm |
| MG-D1133 | MGUIDE conical drill for imp. dia.3.30 L 11.50mm |
| MG-D1137 | MGUIDE conical drill for imp. dia.3.75 L 11.50mm |
| MG-D1142 | MGUIDE conical drill for imp. dia.4.20 L 11.50mm |
| MG-D1150 | MGUIDE conical drill for imp. dia.5 L 11.50mm |
| MG-D1324 | MGUIDE pilot drill dia.2.40 L 13mm |
| MG-D1333 | MGUIDE conical drill for imp. dia.3.30 L 13mm |
| MG-D1337 | MGUIDE conical drill for imp. dia.3.75 L 13mm |
| MG-D1342 | MGUIDE conical drill for imp. dia.4.20 L 13mm |
| MG-D1350 | MGUIDE conical drill for imp. dia.5 L 13mm |
| MG-K001 | MGUIDE set for Seven implant procedure |
| MG-K003 | MGUIDE kit for universal pilot drills |
| MG-KD01 | MGUIDE drills kit for Seven implant procedure |
| MG-KD04 | MGUIDE drills kit for C1 implant procedure |
| MG-N0624 | MGUIDE narrow pilot drill dia.2.40 L 6mm |
| MG-N0633 | MGUIDE narrow conical drill for imp. dia.3.30 L 6mm |
| MG-N0637 | MGUIDE narrow conical drill for imp. dia.3.75 L 6mm |
| MG-N0824 | MGUIDE narrow pilot drill dia.2.40 L 8mm |
| MG-N0833 | MGUIDE narrow conical drill for imp. dia.3.30 L 8mm |
| MG-N0837 | MGUIDE narrow conical drill for imp. dia.3.75 L 8mm |
| MG-N1024 | MGUIDE narrow pilot drill dia.2.40 L 10mm |
| MG-N1033 | MGUIDE narrow conical drill for imp. dia.3.30 L 10mm |
| MG-N1037 | MGUIDE narrow conical drill for imp. dia.3.75 L 10mm |
| MG-N1124 | MGUIDE narrow pilot drill dia.2.40 L 11.50mm |
| MG-N1133 | MGUIDE narrow conical drill for imp. dia.3.30 L 11.50mm |
| MG-N1137 | MGUIDE narrow conical drill for imp. dia.3.75 L 11.50mm |
| MG-N1324 | MGUIDE narrow pilot drill dia.2.40 L 13mm |
| MG-N1333 | MGUIDE narrow conical drill for imp. dia.3.30 L 13mm |
| MG-N1337 | MGUIDE narrow conical drill for imp. dia.3.75 L 13mm |
| MG-NBM40 | MGUIDE narrow bone mill dia.4mm |
| MG-NLG40 | MGUIDE narrow drill length gauge dia.4mm |
| MG-NTP40 | MGUIDE narrow tissue punch dia.4mm |
| MG-TP047 | MGUIDE tissue punch dia.4.7mm |
| MG-TP055 | MGUIDE tissue punch dia.5.5mm |
| MK-0014 | The Basic surgical kit |
| MK-0016 | Mountless Basic Surgical Kit |
| MK-0020 | Bone compression kit |
| MK-0021 | Provisional implants kit |
| MK-0035 | Advanced surgical kit |
| MK-0036 | UNO implant surgical kit |
| MK-0044 | Surgical kit for tapered impl. procedure |
| MK-0045 | External hexagon surgical kit |
| MK-0046 | C1 introduction kit |
| MK-0048 | Seven Internal surgical kit |
| MK-0049 | Lance int. hex. surgical kit |
| MK-BH26 | Bone harvest kit |
| MK-EI35 | Advanced surgical kit with ext. irr. drills |

| Catalog Number | Description |
|-----------------------|--|
| MK-EI48 | Surgical kit for Seven impl. system with ext. irr. drill |
| MK-IR35 | Advanced surgical kit with int. irr. drills |
| MO-CO160 | Convex compress screw 1.80;2.90mm |
| MO-CO200 | Convex compress screw 2.30;3.30mm |
| MO-CO240 | Convex compress screw 2.70;3.70mm |
| MO-CO280 | Convex compress screw 3.10;4.50mm |
| MO-SO300 | Concave sinus screw 3mm |
| MO-SO350 | Concave sinus screw 3.50mm |
| MO-SO400 | Concave sinus screw 4mm |
| MT-00400 | Trephine bur 4mm |
| MT-00500 | Trephine bur 5mm |
| MT-00600 | Trephine bur 6mm |
| MT-BC280 | Bone harvest drill dia. 2.80mm |
| MT-BC320 | Bone harvest drill dia. 3.20mm |
| MT-BC380 | Bone harvest drill dia. 3.80mm |
| MT-BC450 | Bone harvest drill dia. 4.50mm |
| MT-C0642 | Conical drill dia.3.30-4.10 mm for imp. dia.4.20 L 6mm |
| MT-C0650 | Conical drill dia.4.10-4.90 mm for imp. dia.5 L 6mm |
| MT-C0660 | Conical drill for imp. dia.6 L 6mm |
| MT-C0837 | Conical drill dia. 2.80-3.60mm for imp. dia. 3.75 L 8mm |
| MT-C0842 | Conical drill dia. 3.30-4.10mm for imp. dia. 4.20 L 8mm |
| MT-C0850 | Conical drill dia. 4.10-4.90mm for imp. dia. 5 L 8mm |
| MT-C0860 | Conical drill for imp. dia.6 L 8mm |
| MT-C1033 | Conical drill dia. 2.20-3.20mm for imp.dia.3.30 L 10mm |
| MT-C1037 | Conical drill dia. 2.80-3.60mm for imp. dia. 3.75 L 10mm |
| MT-C1042 | Conical drill dia. 3.30-4.10mm for imp. dia. 4.20 L 10mm |
| MT-C1050 | Conical drill dia. 4.10-4.90mm for imp. dia. 5 L 10mm |
| MT-C1060 | Conical drill for imp. dia.6 L 10mm |
| MT-C1133 | Conical drill dia. 2.20-3.20mm for imp.dia.3.30 L 11.5mm |
| MT-C1137 | Conical drill dia. 2.80-3.60mm for imp.dia.3.75 L 11.5mm |
| MT-C1142 | Conical drill dia. 3.30-4.10mm for imp.dia.4.20 L 11.5mm |
| MT-C1150 | Conical drill dia. 4.10-4.90mm for imp. dia. 5 L 11.50mm |
| MT-C1160 | Conical drill for imp. dia.6 L 11.5mm |
| MT-C1333 | Conical drill dia. 2.20-3.20mm for imp. dia. 3.30 L 13mm |
| MT-C1337 | Conical drill dia. 2.80-3.60mm for imp. dia. 3.75 L 13mm |
| MT-C1342 | Conical drill dia. 3.30-4.10mm for imp. dia. 4.20 L 13mm |
| MT-C1350 | Conical drill dia. 4.10-4.90mm for imp. dia. 5 L 13mm |
| MT-C1360 | Conical drill for imp. dia.6 L 13mm |
| MT-C1633 | Conical drill dia. 2.20-3.20mm for imp. dia. 3.30 L 16mm |
| MT-C1637 | Conical drill dia. 2.80-3.60mm for imp. dia. 3.75 L 16mm |
| MT-C1642 | Conical drill dia. 3.30-4.10mm for imp. dia. 4.20 L 16mm |
| MT-C1650 | Conical drill dia. 4.10-4.90mm for imp. dia. 5 L 16mm |
| MT-C2406 | Pilot drill with built in stopper dia.2.40 height 6mm |
| MT-C2408 | Pilot drill with built in stopper dia.2.40 height 8mm |
| MT-C2410 | Pilot drill with built in stopper dia.2.40 height 10mm |
| MT-C2411 | Pilot drill with built in stopper dia.2.40 height 11.5mm |
| MT-C2413 | Pilot drill with built in stopper dia.2.40 height 13mm |
| MT-C2416 | Pilot drill dia.2.40 height 16mm |

| Catalog Number | Description |
|----------------|--|
| MT-C3310 | Conical drill dia.2.4-3.3mm for imp. dia.3.3 L 10mm |
| MT-C3311 | Conical drill dia.2.4-3.3mm for imp. dia.3.3 L 11.5mm |
| MT-C3313 | Conical drill dia.2.4-3.3mm for imp. dia.3.3 L 13mm |
| MT-C3316 | Conical drill dia.2.4-3.3mm for imp. dia.3.3 L 16mm |
| MT-C3708 | Conical drill dia.3-3.60mm for imp. dia.3.75 L 8mm |
| MT-C3710 | Conical drill dia.3-3.60mm for imp. dia.3.75 L 10mm |
| MT-C3711 | Conical drill dia.3-3.60mm for imp. dia.3.75 L 11.5mm |
| MT-C3713 | Conical drill dia.3-3.60mm for imp. dia.3.75 L 13mm |
| MT-C3716 | Conical drill dia.3-3.60mm for imp. dia.3.75 L 16mm |
| MT-C4208 | Conical drill dia.3.5-4.1mm for imp. dia.4.20 L 8mm |
| MT-C4210 | Conical drill dia.3.5-4.1mm for imp. dia.4.20 L 10mm |
| MT-C4211 | Conical drill dia.3.5-4.1mm for imp. dia.4.20 L 11.5mm |
| MT-C4213 | Conical drill dia.3.5-4.1mm for imp. dia.4.20 L 13mm |
| MT-C4216 | Conical drill dia.3.5-4.1mm for imp. dia.4.20 L 16mm |
| MT-CD310 | Conical final drill 3.10mm |
| MT-CD365 | Conical final drill 3.65mm |
| MT-CD410 | Conical final drill 4.10mm |
| MT-CD475 | Conical final drill 4.75mm |
| MT-CD490 | Conical final drill 4.90 mm |
| MT-CRD20 | Ceramic pilot drill dia. 2mm |
| MT-CRD21 | Ceramic marking drill dia. 2.10mm |
| MT-CRD28 | Ceramic twist drill dia. 2.80mm |
| MT-CS410 | Countersink 4.10mm |
| MT-CS450 | Shoulder reamer |
| MT-CSN33 | Countersink for NP |
| MT-GDN33 | Countersink for standard platform |
| MT-GDN50 | Countersink for wide platform |
| MT-M0841 | Final drill for Mistral imp. dia.4.10 L 8mm |
| MT-M0848 | Final drill for Mistral imp. dia.4.80 L 8mm |
| MT-M1041 | Final drill for Mistral imp. dia.4.10 L 10mm |
| MT-M1048 | Final drill for Mistral imp. dia.4.80 L 10mm |
| MT-M1141 | Final drill for Mistral imp. dia.4.10 L 11.5mm |
| MT-M1148 | Final drill for Mistral imp. dia.4.80 L 11.5mm |
| MT-M1341 | Final drill for Mistral imp. dia.4.10 L 13mm |
| MT-M1348 | Final drill for Mistral imp. dia.4.80 L 13mm |
| MT-M1641 | Final drill for Mistral imp. dia.4.10 L 16mm |
| MT-M1648 | Final drill for Mistral imp. dia.4.80 L 16mm |
| MT-P2406 | Pilot drill with built in stopper dia.2.40 height 6mm |
| MT-P2408 | Pilot drill with built in stopper dia.2.40 height 8mm |
| MT-P2410 | Pilot drill with built in stopper dia.2.40 height 10mm |
| MT-P2411 | Pilot drill with built in stopper dia.2.40 height 11.5mm |
| MT-P2413 | Pilot drill with built in stopper dia.2.40 height 13mm |
| MT-P2416 | Pilot drill with built in stopper dia.2.40 height 16mm |
| MT-PD440 | Position drill dia. 4 mm |
| MT-SMD10 | Spade marking drill |
| MT-SUD15 | Single use marking drill |
| MT-SUD20 | Single use drill 2.0 mm |
| MT-SUD28 | Single use drill 2.80 mm |

| Catalog Number | Description |
|----------------|---|
| MT-SUD32 | Single use drill 3.20 mm |
| MT-SUD38 | Single use drill 3.80 mm |
| MT-SUD45 | Single use drill 4.50 mm |
| MT-SUD50 | Single use drill 5.0 mm |
| MT-SUD55 | Single use drill 5.50 mm |
| MT-TD110 | Marking drill 1.90mm |
| MT-TD140 | Drill 1.40mm |
| MT-TD200 | Pilot drill 2mm |
| MT-TD240 | Twist drill 2.40mm |
| MT-TD280 | Twist drill 2.80mm |
| MT-TD300 | Twist drill 3mm |
| MT-TD320 | Twist drill 3.20mm |
| MT-TD350 | Twist drill 3.50mm |
| MT-TD380 | Twist drill 3.80mm |
| MT-TD400 | Twist drill 4mm |
| MT-TD450 | Twist drill 4.50mm |
| MT-TD500 | Twist drill 5mm |
| MT-TD550 | Twist drill 5.50mm |
| MT-TDI28 | Twist short drill 2.80mm |
| MT-TDI30 | Twist short drill 3mm |
| MT-TDI32 | Twist short drill 3.20mm |
| MT-TDI35 | Twist short drill 3.50mm |
| MT-TDI38 | Twist short drill 3.80mm |
| MT-TDI40 | Twist short drill 4mm |
| MT-TDI45 | Twist short drill 4.50mm |
| MT-TDI50 | Twist short drill 5mm |
| MT-TDI55 | Twist short drill 5.50mm |
| MT-TDN19 | Marking drill 1.90mm external irrigation |
| MT-TDN20 | Pilot drill 2mm external irrigation |
| MT-TDN24 | Twist drill 2.40mm external irrigation |
| MT-TDN28 | Twist drill 2.80mm external irrigation |
| MT-TDN30 | Twist drill 3mm external irrigation |
| MT-TDN32 | Twist drill 3.20mm external irrigation |
| MT-TDN35 | Twist drill 3.50mm external irrigation |
| MT-TDN38 | Twist drill 3.80mm external irrigation |
| MT-TDN40 | Twist drill 4mm external irrigation |
| MT-TDN45 | Twist drill 4.50mm external irrigation |
| MT-TDN50 | Twist drill 5mm external irrigation |
| MT-TDN55 | Twist drill 5.50mm external irrigation |
| MT-TDO01 | Ortho anchor pilot drill 1mm |
| MT-TDR24 | Milling drill repair dia. 2.4mm |
| MT-TDS20 | Pilot drill 2mm short |
| MT-TDS28 | Twist drill 2.80mm short |
| MT-TDS32 | Twist drill 3.20mm short |
| MT-TDS45 | Twist drill 4.50mm short |
| MT-TDT28 | Twist drill 2.80mm external irrigation (red) |
| MT-TDT30 | Twist drill 3mm external irrigation (red) |
| MT-TDT32 | Twist drill 3.20mm external irrigation (blue) |

| Catalog Number | Description |
|----------------|---|
| MT-TDT35 | Twist drill 3.5mm external irrigation (blue) |
| MT-TDT38 | Twist drill 3.80mm external irrigation (blue) |
| MT-TDT40 | Twist drill 4mm external irrigation (green) |
| MT-TDT45 | Twist drill 4.50mm external irrigation (white) |
| MT-TDT50 | Twist drill 5mm external irrigation (white) |
| MT-TDT55 | Twist drill 5.50mm external irrigation (white) |
| MT-TP420 | Tissue punch for 4.20mm dia implant |
| CT-TDN30 | Step drill Ø3\2.4mm, external irrigation (red) |
| CT-TDN35 | Step drill 3.5\3mmmm external irrigation (blue) |
| CT-TDN40 | Step drill 4\3mmmm external irrigation (green) |
| MG-DFP20 | MGUIDE drill for fixation pin, dia. 2 mm |
| MG-DLG55 | MGUIDE drill length gauge dia.5.50mm |
| MG-P0624 | MGUIDE universal pilot drill dia.2.40 L 6mm |
| MG-P0824 | MGUIDE universal pilot drill dia.2.40 L 8mm |
| MG-P1024 | MGUIDE universal pilot drill dia.2.40 L 10mm |
| MG-P1124 | MGUIDE universal pilot drill dia.2.40 L 11.5mm |
| MG-P1324 | MGUIDE universal pilot drill dia.2.40 L 13mm |
| MT-F0839 | Conical step drill for imp. dia.3.90 L 8mm |
| MT-F0843 | Conical step drill for imp. dia.4.30 L 8mm |
| MT-F0850 | Conical step drill for imp. dia.5 L 8mm |
| MT-F1033 | Conical step drill for imp. dia.3.30 L 10mm |
| MT-F1039 | Conical step drill for imp. dia.3.90 L 10mm |
| MT-F1043 | Conical step drill for imp. dia.4.30 L 10mm |
| MT-F1050 | Conical step drill for imp. dia.5 L 10mm |
| MT-F1133 | Conical step drill for imp. dia.3.30 L 11.50mm |
| MT-F1139 | Conical step drill for imp. dia.3.90 L 11.50mm |
| MT-F1143 | Conical step drill for imp. dia.4.30 L 11.50mm |
| MT-F1150 | Conical step drill for imp. dia.5 L 11.50mm |
| MT-F1333 | Conical step drill for imp. dia.3.30 L 13mm |
| MT-F1339 | Conical step drill for imp. dia.3.90 L 13mm |
| MT-F1343 | Conical step drill for imp. dia.4.30 L 13mm |
| MT-F1350 | Conical step drill for imp. dia.5 L 13mm |
| MT-F1633 | Conical step drill for imp. dia.3.30 L 16mm |
| MT-F1639 | Conical step drill for imp. dia.3.90 L 16mm |
| MT-F1643 | Conical step drill for imp. dia.4.30 L 16mm |
| MT-PDM24 | Position drill mill dia.2.4mm |
| MT-RAD18 | Technical drill dia. 1.80mm |
| MT-RAD23 | Technical drill dia. 2.30mm |
| MG-PBM24 | MGUIDE universal pilot bone mill dia.2.40mm |