
Manufacturer : MegaGen Implant Co., Ltd.

Address : 45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun, Daegu 42921, Republic of Korea

Product : **MiNi Internal Implant System**
of Dental Implant system is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore patient's chewing function.

GMDN Code : Screw endosteal dental implant (GMDN # 55849)
Dental Implant Superstructure (GMDN # 44879,44880,44881)
Dental attachment (GMDN #38576)

Classification (MDD Annex IX) : Screw endosteal dental implant, (IIb, Rule 8)
Dental Implant Superstructure (IIb, Rule 8)
Dental attachment (IIa, Rule 5)

We herewith declare under our sole responsibility that the above mentioned product meets all the essential requirements of the following EC Council Directive and the provisions of the following Standards. We herewith declare that we are exclusively responsible for the declaration of conformity. All supporting documentation is retained under the promises of the manufacturer and the notified body.

Regulations

Council Directive 93/42/EEC as amended by 2007/47/EC of 5 September 2007 concerning medical devices(MDD 2007/47/EC)

Standards :

Standards applicable to this product are :

EN ISO 13485:2016, EN ISO 14971:2012, EN 1642:2011, ISO 10993-1:2009/AC:2010, ISO 14801:2016, EN 556-1:2001/AC:2006, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11737-1:2006/AC:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 17665-1:2006, ASTM F67-13, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 10993-12:2012, ASTM F1980-16, EN ISO 11737-2:2009, ASTM F88/F88M-15, MEDDEV 2.7.1 Rev.4, ISO 14644-1:2015, ASTM F136-13, ASTM F899-12b, ASTM F1537-11, ISO 22674:2016, ISO/TS 17665-2:2009,

Notified body : DNV GL Nemko Presafe AS
Identification No.2460 Veritasveien 3 1363 Høvik Norway
(NB number 2460)

Conformity Assessment Route : Council Directive 93/42/EEC as amended by Directive 2007/47/EC Annex II excluding section 4

EC Authorized Representative MDSS GmbH
Schiffgraben 41 30175 Hannover, Germany

This declaration is valid for the above mentioned CE-marked products after the signature date below and until the expiration of the EC-Certificate No.10888-2017-CE-KOR-NA-PS Rev 7.0 issued by DNV GL NEMKO PRESAFE AS (Valid until: 27 May 2024).

Place, Issued date : MegaGen Implant Co., Ltd in KOREA, December 24, 2020
Model Name :
Lot Number (S/N):

Signature : 

Name : Kwang-Bum Park
Position : CEO / President
MegaGen Implant Co., Ltd.

Attachment 1–Product list

1. Dental Implant

Product	Model name	Reference code	UDI-DI
MiNi Internal Fixture	MIIF3010	MIIF3010C	08806388226849
MiNi Internal Fixture	MIIF3011	MIIF3011C	08806388226863
MiNi Internal Fixture	MIIF3013	MIIF3013C	08806388226887
MiNi Internal Fixture	MIIF3015	MIIF3015C	08806388226900
MiNi Internal Fixture	MIIF3308	MIIF3308C	08806388226924
MiNi Internal Fixture	MIIF3310	MIIF3310C	08806388226948
MiNi Internal Fixture	MIIF3311	MIIF3311C	08806388226962
MiNi Internal Fixture	MIIF3313	MIIF3313C	08806388226986
MiNi Internal Fixture	MIIF3315	MIIF3315C	08806388227006

2. Dental Implant Superstructure

Product	Model name	Reference code	UDI-DI
EZ Post Abutment	MI EP3505H	MI EP3505HT	08806388226528
EZ Post Abutment	MI EP3515H	MI EP3515HT	08806388226559
EZ Post Abutment	MI EP3525H	MI EP3525HT	08806388226580
EZ Post Abutment	MI EP3535H	MI EP3535HT	08806388226610
EZ Post Abutment	MI EP3545H	MI EP3545HT	08806388226641
EZ Post Abutment	MI EP3507H	MI EP3507HT	08806388226535
EZ Post Abutment	MI EP3517H	MI EP3517HT	08806388226566
EZ Post Abutment	MI EP3527H	MI EP3527HT	08806388226597
EZ Post Abutment	MI EP3537H	MI EP3537HT	08806388226627
EZ Post Abutment	MI EP3547H	MI EP3547HT	08806388226658
EZ Post Abutment	MI EP3509H	MI EP3509HT	08806388226542
EZ Post Abutment	MI EP3519H	MI EP3519HT	08806388226573
EZ Post Abutment	MI EP3529H	MI EP3529HT	08806388226603
EZ Post Abutment	MI EP3539H	MI EP3539HT	08806388226634
EZ Post Abutment	MI EP3549H	MI EP3549HT	08806388226665
Milling Abutment	MIMA3005H	MIMA3005HT	08806388227129
Milling Abutment	MIMA3015H	MIMA3015HT	08806388227150
Milling Abutment	MIMA3025H	MIMA3025HT	08806388227181
Milling Abutment	MIMA3035H	MIMA3035HT	08806388227211
Milling Abutment	MIMA3045H	MIMA3045HT	08806388227242
Milling Abutment	MIMA3007H	MIMA3007HT	08806388227136
Milling Abutment	MIMA3017H	MIMA3017HT	08806388227167
Milling Abutment	MIMA3027H	MIMA3027HT	08806388227198
Milling Abutment	MIMA3037H	MIMA3037HT	08806388227228
Milling Abutment	MIMA3047H	MIMA3047HT	08806388227259
Milling Abutment	MIMA3009H	MIMA3009HT	08806388227143
Milling Abutment	MIMA3019H	MIMA3019HT	08806388227174
Milling Abutment	MIMA3029H	MIMA3029HT	08806388227204
Milling Abutment	MIMA3039H	MIMA3039HT	08806388227235
Milling Abutment	MIMA3049H	MIMA3049HT	08806388227266
Milling Abutment	MIMA3505H	MIMA3505HT	08806388227273
Milling Abutment	MIMA3515H	MIMA3515HT	08806388227303
Milling Abutment	MIMA3525H	MIMA3525HT	08806388227334
Milling Abutment	MIMA3535H	MIMA3535HT	08806388227365
Milling Abutment	MIMA3545H	MIMA3545HT	08806388227396
Milling Abutment	MIMA3507H	MIMA3507HT	08806388227280

Milling Abutment	MIMA3517H	MIMA3517HT	08806388227310
Milling Abutment	MIMA3527H	MIMA3527HT	08806388227341
Milling Abutment	MIMA3537H	MIMA3537HT	08806388227372
Milling Abutment	MIMA3547H	MIMA3547HT	08806388227402
Milling Abutment	MIMA3509H	MIMA3509HT	08806388227297
Milling Abutment	MIMA3519H	MIMA3519HT	08806388227327
Milling Abutment	MIMA3529H	MIMA3529HT	08806388227358
Milling Abutment	MIMA3539H	MIMA3539HT	08806388227389
Milling Abutment	MIMA3549H	MIMA3549HT	08806388227419
Solid Abutment	MISA3005	MISA3005	08806388227440
Solid Abutment	MISA3015	MISA3015	08806388227471
Solid Abutment	MISA3025	MISA3025	08806388227501
Solid Abutment	MISA3035	MISA3035	08806388227532
Solid Abutment	MISA3045	MISA3045	08806388227563
Solid Abutment	MISA3007	MISA3007	08806388227457
Solid Abutment	MISA3017	MISA3017	08806388227488
Solid Abutment	MISA3027	MISA3027	08806388227518
Solid Abutment	MISA3037	MISA3037	08806388227549
Solid Abutment	MISA3047	MISA3047	08806388227570
Solid Abutment	MISA3009	MISA3009	08806388227464
Solid Abutment	MISA3019	MISA3019	08806388227495
Solid Abutment	MISA3029	MISA3029	08806388227525
Solid Abutment	MISA3039	MISA3039	08806388227556
Solid Abutment	MISA3049	MISA3049	08806388227587
Solid Abutment	MISA3505	MISA3505	08806388227594
Solid Abutment	MISA3515	MISA3515	08806388227624
Solid Abutment	MISA3525	MISA3525	08806388227655
Solid Abutment	MISA3535	MISA3535	08806388227686
Solid Abutment	MISA3545	MISA3545	08806388227716
Solid Abutment	MISA3507	MISA3507	08806388227600
Solid Abutment	MISA3517	MISA3517	08806388227631
Solid Abutment	MISA3527	MISA3527	08806388227662
Solid Abutment	MISA3537	MISA3537	08806388227693
Solid Abutment	MISA3547	MISA3547	08806388227723
Solid Abutment	MISA3509	MISA3509	08806388227617
Solid Abutment	MISA3519	MISA3519	08806388227648
Solid Abutment	MISA3529	MISA3529	08806388227679
Solid Abutment	MISA3539	MISA3539	08806388227709

Solid Abutment	MISA3549	MISA3549	08806388227730
Angled Abutment	MIAA3215H	MIAA3215HT	08806388226351
Angled Abutment	MIAA3315H	MIAA3315HT	08806388226375
Angled Abutment	MIAA3415H	MIAA3415HT	08806388226399
Angled Abutment	MIAA3215E	MIAA3215ET	08806388226344
Angled Abutment	MIAA3315E	MIAA3315ET	08806388226368
Angled Abutment	MIAA3415E	MIAA3415ET	08806388226382
Meg-Rhein Abutment	MDR00	MDR00	08806388225750
Meg-Rhein Abutment	MDR01	MDR01	08806388225774
Meg-Rhein Abutment	MDR02	MDR02	08806388225798
Meg-Rhein Abutment	MDR03	MDR03	08806388225811
Meg-Rhein Abutment	MDR04	MDR04	08806388225835
Meg-Rhein Abutment	MDR05	MDR05	08806388225873
Meg-Rhein Abutment	MDR06	MDR06	08806388225897
Meg-Rhein Overdenture System	MDR00P	MDR00P	08806388225767
Meg-Rhein Overdenture System	MDR01P	MDR01P	08806388225781
Meg-Rhein Overdenture System	MDR02P	MDR02P	08806388225804
Meg-Rhein Overdenture System	MDR03P	MDR03P	08806388225828
Meg-Rhein Overdenture System	MDR04P	MDR04P	08806388225842
Meg-Rhein Overdenture System	MDR05P	MDR05P	08806388225880
Meg-Rhein Overdenture System	MDR06P	MDR06P	08806388225903
Meg-Rhein Overdenture System	MDR00PA	MDR00PA	08806388271368
Meg-Rhein Overdenture System	MDR01PA	MDR01PA	08806388271375
Meg-Rhein Overdenture System	MDR02PA	MDR02PA	08806388271382
Meg-Rhein Overdenture System	MDR03PA	MDR03PA	08806388271399
Meg-Rhein Overdenture System	MDR04PA	MDR04PA	08806388271405
Meg-Rhein Overdenture System	MDR05PA	MDR05PA	08806388271412
Meg-Rhein Overdenture System	MDR06PA	MDR06PA	08806388271429
Meg-Loc Abutment	MLMI00	MLMI00	Not yet
Meg-Loc Abutment	MLMI01	MLMI01	Not yet
Meg-Loc Abutment	MLMI02	MLMI02	Not yet
Meg-Loc Abutment	MLMI03	MLMI03	Not yet
Meg-Loc Abutment	MLMI04	MLMI04	Not yet
Meg-Loc Abutment	MLMI05	MLMI05	Not yet
Meg-Loc Abutment	MLMI06	MLMI06	Not yet
Meg-Loc Abutment	MLMI07	MLMI07	Not yet
Meg-Ball Abutment	MBMI00	MBMI00	Not yet
Meg-Ball Abutment	MBMI10	MBMI10	Not yet

Meg-Ball Abutment	MBMI20	MBMI20	Not yet
Meg-Ball Abutment	MBMI30	MBMI30	Not yet
Meg-Ball Abutment	MBMI40	MBMI40	Not yet
Meg-Ball Abutment	MBMI50	MBMI50	Not yet
Meg-Ball Abutment	MBMI60	MBMI60	Not yet
Meg-Ball Abutment	MBMI70	MBMI70	Not yet
Meg-Ball Package	MBMI00P	MBMI00P	Not yet
Meg-Ball Package	MBMI10P	MBMI10P	Not yet
Meg-Ball Package	MBMI20P	MBMI20P	Not yet
Meg-Ball Package	MBMI30P	MBMI30P	Not yet
Meg-Ball Package	MBMI40P	MBMI40P	Not yet
Meg-Ball Package	MBMI50P	MBMI50P	Not yet
Meg-Ball Package	MBMI60P	MBMI60P	Not yet
Meg-Ball Package	MBMI70P	MBMI70P	Not yet
TiGEN Abutment	MITNN1016	MITNN1016T	Not yet
		MITNN1016.MTN	Not yet
TiGEN Abutment	MITNN1016N	MITNN1016NT	Not yet
		MITNN1016N.MTN	Not yet
TiGEN Abutment	MITNM1214	MITNM1214T	Not yet
		MITNM1214.MTN	Not yet
TiGEN Abutment	MITNM1214N	MITNM1214NT	Not yet
		MITNM1214N.MTN	Not yet
TiGEN Abutment	MITNR1015	MITNR1015T	Not yet
		MITNR1015.MTN	Not yet
TiGEN Abutment	MITNR1015N	MITNR1015NT	Not yet
		MITNR1015N.MTN	Not yet
TiGEN Abutment	MITN1020	MITN1020T	08806388227945
		MITN1020.MTN	08806388245703
TiGEN Abutment	MITN1020N	MITN1020NT	08806388227921
		MITN1020N.MTN	08806388245710
ZrGEN Abutment	MIPN3013	MIPN3013T	08806388227433
		MIPN3013.MTN	08806388245031
ZrGEN Abutment	MIPN3013N	MIPN3013NT	08806388227426
		MIPN3013N.MTN	08806388245048
Cover Screw	MICS2505	MICS2505	08806388226436
Healing Abutment	MIHA3025	MIHA3025	08806388226719
Healing Abutment	MIHA3030	MIHA3030	08806388226726
Healing Abutment	MIHA3040	MIHA3040	08806388226733

Healing Abutment	MIHA3050	MIHA3050	08806388226740
Healing Abutment	MIHA3060	MIHA3060	08806388226757
Healing Abutment	MIHA3070	MIHA3070	08806388275168
Healing Abutment	MIHA3080	MIHA3080	08806388275175
Healing Abutment	MIHA3090	MIHA3090	08806388275182
Healing Abutment	MIHA3525	MIHA3525	08806388226764
Healing Abutment	MIHA3530	MIHA3530	08806388226771
Healing Abutment	MIHA3540	MIHA3540	08806388226788
Healing Abutment	MIHA3550	MIHA3550	08806388226795
Healing Abutment	MIHA3560	MIHA3560	08806388226801
Healing Abutment	MIHA3570	MIHA3570	08806388275199
Healing Abutment	MIHA3580	MIHA3580	08806388275205
Healing Abutment	MIHA3590	MIHA3590	08806388275212
Temporary Abutment	MITA3012H	MITA3012HT	08806388227754
Temporary Abutment	MITA3012N	MITA3012NT	08806388227761
Temporary Abutment	MNTAH35210	MNTAH35210T	Not yet
Temporary Abutment	MNTAH35310	MNTAH35310T	Not yet
Temporary Abutment	MNTAH35410	MNTAH35410T	Not yet
Temporary Abutment	MNTAH35510	MNTAH35510T	Not yet
Temporary Abutment	MNTAN35210	MNTAN35210T	Not yet
Temporary Abutment	MNTAN35310	MNTAN35310T	Not yet
Temporary Abutment	MNTAN35410	MNTAN35410T	Not yet
Temporary Abutment	MNTAN35510	MNTAN35510T	Not yet
Fuse Abutment	MFAP3535	MFAP3535P	08806388226146
Fuse Abutment	MFAA3315	MFAA3315P	08806388226139
Fuse Abutment	MFAP3545	MFAP3545P	08806388260485
Fuse Abutment	MFAA3415	MFAA3415P	08806388260492
Fuse Cap	MFCP	MFCP	08806388253388
Fuse Cap	MFCA15	MFCA15	08809708754374
Abutment Screw	MIAS14	MIAS14	08806388226405
Abutment Screw	MIAZ1410	MIAZ1410	08806388226412

3. Dental Attachment

Product	Model name	Reference code	UDI-DI
Retentive Cap	RCVP	RCVP	08806388231409
Retentive Cap	RCWP	RCWP	08806388231416
Retentive Cap	RCPP	RCPP	08806388231355
Retentive Cap	RCYP	RCYP	08806388231423
Retentive Cap	RCBP	RCBP	08806388231003
Retentive Cap	140CEV	140CEV	08806388299591
Retentive Cap	140CET	140CET	08806388299959
Retentive Cap	140CER	140CER	08806388299966
Retentive Cap	140CEG	140CEG	08806388299973
Retentive Cap	140CEN	140CEN	08806388299980
Retentive Ring	MBR	MBR	08806388260683
Retentive Ring	MBR	MBR5	08806388275700
Retentive Ring	MBR	MBR10	08806388275717
Stainless Steel Housing	141CAE4	141CAE4	08806388299997
Stainless Steel Housing	MHP	MHP	08806388226337
Stainless Steel Housing	TH	TH	08809708750932
Stainless Steel Housing	THP	THP	08806388256853
Metal Cap	MBH	MBH	08809708750949
Metal Housing	MBHR	MBHR	08806388275724
Meg-Rhein Overdenture system	MP	MP	08806388228218
Meg-Rhein Overdenture system	MPA	MPA	08806388260676