ARUM DENTISTRY Co., Ltd.
1-dong, 44, Techno 8-ro, Yuseong-gu, Daejeon, 34028, Republic of Korea

EC Declaration of Conformity

This Declaration of Conformity is issued under the sole responsibility of ARUM DENTISTRY Co., Ltd. The device covered by the present EU declaration is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by directive 2007/47/EC and with the EN ISO 13485.

Manufacturer	ARUM DENTISTRY Co., Ltd. 1-dong, 44, Techno-8ro Yuseong-gu, Daejeon, 34028, Rep. of Korea Tel : +82-42-935-3644 Homepage : www.arumdentistry.com
Device Name	Dental abutment and prosthetic screw
Brand Name	Custom Abutment
Intended Use	The Custom Abutment (Pre-milled Blank) CAD/CAM System is intended for the design and fabrication of dental restorations by dental laboratories by means of a digital workflow.
Classification	Class IIb (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 8)
Model Name	Total 964 models including CIHE001 (Refer to the Annex II)
GMDN Code	44879 [Abutment, implant, dental, endosseous]
Conformity Assessment Route	Annex II Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC
Notified Body	Bureau Veritas Italia S.p.A. (Notified Body No. 1370) Viale Monza, 347- 20126 Milano (MI), Italy
Applied Standards	Refer to the Annex I
EC Representative	MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany
EC Certificate	IT273199-2 (Expiry date 2023.03.23)

CE
1370

Place and Date : Daejeon 2021.05.20 **Signature :**

LEE Jeong Hyun / President

Annex I. Applied Standards

No.	Standard	Standard Name
1	EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	93/42/EEC amended by Directive 2007/47/EC	September 2007 concerning medical devices
3	ASTM F136	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications
4	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
5	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
6	ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971
7	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
8	EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
9	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
10	EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
11	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
12	EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
13	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
14	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
15	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference
16	EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
17	ISO 14801:2016	Dentistry - Implants - Dynamic fatigue test for endosseous dental implants
18	ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration

19	ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
20	EN ISO 17665-1:2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
21	IEC 62366-1:2015/AMD:2020	Medical devices - Part 1: Application of usability engineering to medical devices
22	NBMed 2.12 rec 1	PMS Sources
23	MEDDEV 2.12-1 Rev. 8	Guidelines on a medical device vigilance system
24	MEDDEV 2.12-2 Rev. 2	Post market clinical follow up
25	MEDDEV 2.4/1 Rev. 9	Guidelines relating to the application of the council directive 93/42/EEC on medical devices
26	MEDDEV 2.5/10	Guideline for Authorized Representatives
27	MEDDEV 2.7.1 Rev. 4	Evaluation of clinical data

Annex II. Model Name

1) Custom Abutment

CIHE001	CIHE002	CIHE003	CIHE004	CIHE005
CIHE006	CIHE007	CIHE008	CIHE009	CIHE010
CIHE011	CIHE012	CIHE013	CIHE014	CIHE015
CIHE016	CIHE017	CIHE018	CIHE019	CIHE020
CIHE021	CIHE022	CIHE023	CIHE024	CIHE025
CIHE026	CIHE027	CIHE028	CIHE029	CIHE030
CIHE031	CIHE032	CIHE033	CIHE034	CIHE035
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CIHE041	CIHE042	CIHE043	CIHE044	CIHE045
CIHE046	CIHE047	CIHE048	CIHE049	CIHE050
CIHE051	CIHE052	CIHE053	CIHE054	CIHE055
CIHE056	CIHE057	CIHE058	CIHE059	CIHE060
CIHE061	CIHE062	CIHE063	CIHE064	CIHE065
CIHE066	CIHE067	CIHE068	CIHE069	CIHE070
CIHE071	CIHE072	CIHE073	CIHE074	CIHE075
CIHE076	CIHE077	CIHE078	CIHE079	CIHE080
CIHE081	CIHE082	CIHE083	CIHE084	CIHE085
CIHE086	CIHE087	CIHE088	CIHE089	CIHE090
CIHE091	CIHE092	CIHE093	CIHE094	CIHE095
CIHE096	CIHE097	CIHE098	CIHE099	CIHE100
CIHE101	CIHE102	CIHE103	CIHE104	CIHE105
CIHE106	CIHE107	CIHE108	CIHE109	CIHE110
CIHE111	CIHE112	CIHE113	CIHE114	CIHE115
CIHE116	CIHE117	CIHE118	CIHE119	CIHE120
CIHE121	CIHE122	CIHE123	CIHE124	CIHE125
CIHE126	CIHE127	CIHE128	CIHE129	CIHE130
CIHE131	CIHE132	CIHE133	CIHE134	CIHE135
CIHE136	CIHE137	CIHE138	CIHE139	CIHE140
CIHE141	CIHE142	CIHE143	CIHE144	CIHE145
CIHE146	CIHE147	CIHE148	CIHE149	CIHE150
CIHE151	CIHE152	CIHE153	CIHE154	CIHE155
CIHE156	CIHE157	CIHE158	CIHE159	CIHE160
CIHE166	CIHE167	CIHE168	CIHE169	CIHE170
CIHE171	CIHE172	CIHE173	CIHE174	CIHE175

CIHE176	CIHE177	CIHE178	CIHE179	CIHE180
CIHE181	CIHE182	CIHE183	CIHE184	CIHE185
CIHE186	CIHE187	CIHE188	CIHE189	CIHE190
CIHE191	CIHE192	CIHE193	CIHE194	CIHE197
CIHE198	CIHE199	CIHE200	CIHE201	CIHE202
CIHE203	CIHE204			

CINH001	CINH002	CINH003	CINH004	CINH005
CINH006	CINH007	CINH008	CINH009	CINH010
CINH011	CINH012	CINH013	CINH014	CINH015
CINH016	CINH017	CINH018	CINH019	CINH020
CINH021	CINH022	CINH023	CINH024	CINH025
CINH026	CINH027	CINH028	CINH029	CINH030
CINH031	CINH032	CINH033	CINH034	CINH035
CINH036	CINH037	CINH038	CINH039	CINH040
CINH041	CINH042	CINH043	CINH044	CINH045
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CINH076	CINH077	CINH078	CINH079	CINH080
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CINH091	CINH092	CINH093	CINH094	CINH095
CINH096	CINH097	CINH098	CINH099	CINH100
CINH101	CINH102	CINH103	CINH104	CINH105
CINH106	CINH107	CINH108	CINH109	CINH110
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CINH146	CINH147	CINH148	CINH149	CINH150
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CINH156	CINH157	CINH158	CINH159	CINH160
CINH161	CINH162	CINH163	CINH164	CINH165
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CINH171	CINH172	CINH173	CINH174	CINH175
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CINH216	CINH217	CINH218	CINH219	CINH220
CINH221	CINH222	CINH223	CINH224	CINH225
CINH226	CINH227	CINH228	CINH229	CINH230
CINH231	CINH232	CINH233	CINH234	CINH235
CINH236	CINH237	CINH238	CINH245	CINH246
CINH247	CINH248			

CEHE001	CEHE002	CEHE003	CEHE004	CEHE005
CEHE006	CEHE007	CEHE008	CEHE009	CEHE010
CEHE011	CEHE012	CEHE013	CEHE014	CEHE015
CEHE016	CEHE017	CEHE018	CEHE019	CEHE020
CEHE021	CEHE022	CEHE023	CEHE024	CEHE025
CEHE026	CEHE027	CEHE028	CEHE029	CEHE030
CEHE031	CEHE032	CEHE033	CEHE034	CEHE035
CEHE036	CEHE037	CEHE038	CEHE039	CEHE040
CEHE041	CEHE042	CEHE043	CEHE044	

CENH001	CENH002	CENH003	CENH004	CENH005
CENH006	CENH007	CENH008	CENH009	CENH010
CENH011	CENH012	CENH013	CENH014	CENH015
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CENH026	CENH027	CENH028	CENH029	CENH030

CENH031	CENH032	CENH033	CENH034	CENH035
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CENH041	CENH042	CENH043	CENH044	CENH045
CENH046	CENH047	CENH048	CENH049	CENH050
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CENH056	CENH057	CENH058	CENH059	CENH060
CENH061	CENH062	CENH065	CENH066	CENH067
CENH068	CENH069	CENH070		

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CINO031	CINO032	CINO033	CINO034	CINO035
CINO036				

CITR001	CITR002	CITR003	CITR004	CITR005
CITR006	CITR007	CITR008	CITR009	CITR010
CITR011	CITR012	CITR013	CITR014	CITR015
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CITR026	CITR027	CITR028	CITR029	CITR030
CITR031	CITR032	CITR033	CITR034	CITR035

CITR036	CITR037	CITR038	CITR039	CITR040
CITR041	CITR042	CITR043	CITR044	

CITO001	CITO002	CITO003	CITO004	CITO005
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CITO011	CITO012	CITO013	CITO014	CITO015
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CITO036	CITO037	CITO038	CITO039	CITO040
CITO041	CITO042			

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CISQ016	CISQ017	CISQ018	CISQ019	CISQ020

2) Abutment screw

CSHE001	CSHE002	CSHE003	CSHE004	CSHE005
CSHE006	CSHE007	CSHE008	CSHE009	CSHE010
CSHE011	CSHE012	CSHE013	CSHE014	CSHE015
CSHE016	CSHE017	CSHE018	CSHE019	CSHE020
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CSHE091	CSHE092	CSHE093	CSHE094	CSHE095
CSHE096	CSHE097	CSHE098	CSHE099	CSHE100

CSTO001	CSTO002	CSTO003	CSTO004	CSTO005
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CSTO026	CSTO027	CSTO028	CSTO029	CSTO030
CSTO031	CSTO032	CSTO033	CSTO034	CSTO035

CSCR001	CSCR002

CSHE201	CSHE202	CSHE203	CSHE204	CSHE205
CSHE206	CSHE207	CSHE208	CSHE209	CSHE210
CSHE211	CSHE212	CSHE213	CSHE214	CSHE215
CSHE216	CSHE217			

CSTO201	CSTO202	CSTO203	CSTO204	CSTO205

CSHE301	CSHE302	CSHE303	CSHE304	CSHE305
CSHE306	CSHE307	CSHE308	CSHE309	CSHE310
CSHE311	CSHE312			

CSTO301	CSTO302	CSTO303	CSTO304	CSTO305

CSSQ301	CSSQ302

CSHE401	CSHE402	CSHE403	CSHE404	CSHE405
CSHE406	CSHE407	CSHE408	CSHE409	

CSTO401	CSTO402	CSTO403	CSTO404

CSHE501	CSHE502	CSHE503	CSHE504	CSHE505
CSHE506	CSHE507			

CSTO501	CSTO502	CSTO503	CSTO504	CSTO505

ARUM DENTISTRY Co., Ltd.
1-dong, 44, Techno 8-ro, Yuseong-gu, Daejeon, 34028, Republic of Korea

CSSQ501

CSHE601	CSHE602	CSHE603

CSTO601	CSTO602	CSTO603	CSTO604

CSSQ601

(주)아름덴티스트리 ARUM DENTISTRY Co., Ltd.
대전광역시 유성구 국제과학11로 23(둔곡동 404-3)
23, Gukjegwahak 11-ro, Yuseong-gu, Daejeon, Korea
Tel : 82 42 935 3644 Fax : 82 42 935 3645
www.arumdentistry.com

Declaration of Conformity (DoC) Corrigendum

Product name: Dental abutment and prosthetic screw

Brand name: Custom Abutment

Model name: Total 964 models including CIHE001

Classification: Class IIb (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 8)

Date of the DoC: 2021-05-20

EC Certificate: IT273199-2

Expiry date: March 23, 2023

This corrigendum intends to correct the following information in DoC of the above listed product.

We, ARUM DENTISTRY Co., Ltd. are changed Manufacturing address from *1-dong, 44, Techno 8-ro, Yuseong-gu, Daejeon, Korea* to *23, Gukjegwahak 11-ro, Yuseong-gu, Daejeon, 34002, Republic of Korea* on 20 June 2022.

And, changed EC Representative from MedNet EC-REP GmbH to MedNet EC-REP IIb GmbH on 27 July. Therefore, we hereby corrected the information in the previous DoC.

Name: LEE Jeong Hyeon

Position: CEO

Place and Date: Daejeon 2022-07-27

Signature: