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	Link Abutment
Intended Use	The Link Abutment (Ti-base) 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 636 models including LIHE001 (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
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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) Link Abutment

LIHE001	LIHE002	LIHE003	LIHE004	LIHE005
LIHE006	LIHE007	LIHE008	LIHE009	LIHE010
LIHE011	LIHE012	LIHE013	LIHE014	LIHE015
LIHE016	LIHE017	LIHE018	LIHE019	LIHE020
LIHE021	LIHE022	LIHE023	LIHE024	LIHE025
LIHE026	LIHE027	LIHE028	LIHE029	LIHE030
LIHE031	LIHE032	LIHE033	LIHE034	LIHE035
LIHE036	LIHE037	LIHE038	LIHE039	LIHE040
LIHE041	LIHE042	LIHE043	LIHE044	LIHE045
LIHE046	LIHE047	LIHE048	LIHE049	LIHE050
LIHE051	LIHE052	LIHE053	LIHE054	LIHE055
LIHE056	LIHE057	LIHE058	LIHE059	LIHE060
LIHE061	LIHE062	LIHE063	LIHE064	LIHE065
LIHE066	LIHE067	LIHE068	LIHE069	LIHE070
LIHE071	LIHE072	LIHE073	LIHE074	LIHE075
LIHE076	LIHE077	LIHE078	LIHE079	LIHE080
LIHE081	LIHE082	LIHE083	LIHE084	LIHE085
LIHE086	LIHE087	LIHE088	LIHE089	

LINH001	LINH002	LINH003	LINH004	LINH005
LINH006	LINH007	LINH008	LINH009	LINH010
LINH011	LINH012	LINH013	LINH014	LINH015
LINH016	LINH017	LINH018	LINH019	LINH020
LINH021	LINH022	LINH023	LINH024	LINH025
LINH026	LINH027	LINH028	LINH029	LINH030
LINH031	LINH032	LINH033	LINH034	LINH035
LINH036	LINH037	LINH038	LINH039	LINH040
LINH041	LINH042	LINH043	LINH044	LINH045
LINH046	LINH047	LINH048	LINH049	LINH050
LINH051	LINH052	LINH053	LINH054	LINH055
LINH056	LINH057	LINH058	LINH059	LINH060
LINH061	LINH062	LINH063	LINH064	LINH065
LINH066	LINH067	LINH068	LINH069	LINH070

LINH071	LINH072	LINH073	LINH074	LINH075
LINH076	LINH077	LINH078	LINH079	LINH080
LINH081	LINH082	LINH083	LINH084	LINH085
LINH086	LINH087	LINH088	LINH089	LINH090
LINH091	LINH092	LINH093	LINH094	LINH095
LINH096	LINH097	LINH098	LINH099	LINH100
LINH101	LINH102	LINH103	LINH104	LINH105
LINH106	LINH107	LINH108	LINH109	LINH110
LINH111	LINH112	LINH113	LINH114	LINH115
LINH116	LINH117	LINH118	LINH119	LINH120
LINH121	LINH122	LINH123	LINH124	

LEHE001	LEHE002	LEHE003	LEHE004	LEHE005
LEHE006	LEHE007	LEHE008	LEHE009	LEHE010
LEHE011	LEHE012	LEHE013	LEHE014	LEHE015
LEHE016	LEHE017	LEHE018		

LENH001	LENH002	LENH003	LENH004	LENH005
LENH006	LENH007	LENH008	LENH009	LENH010
LENH011	LENH012	LENH013	LENH014	LENH015
LENH016	LENH017	LENH018	LENH019	LENH020
LENH021	LENH022	LENH023	LENH024	LENH025
LENH026	LENH027	LENH028	LENH029	LENH030
LENH031	LENH032	LENH033	LENH034	LENH035

LIOC001	LIOC002	LIOC003	LIOC004	LIOC005
LIOC006	LIOC007	LIOC008	LIOC009	LIOC010
LIOC011	LIOC012	LIOC013	LIOC014	LIOC015
LIOC016	LIOC017	LIOC018	LIOC019	LIOC020
LIOC021	LIOC022			

LINO001	LINO002	LINO003	LINO004	LINO005
LINO006	LINO007	LINO008	LINO009	LINO010
LINO011	LINO012	LINO013	LINO014	

LITR001	LITR002	LITR003	LITR004	LITR005
LITR006	LITR007	LITR008	LITR009	LITR010

LITR011	LITR012	LITR013	LITR014	LITR015
LITR016	LITR017	LITR018		

LITO001	LITO002	LITO003	LITO004	LITO005
LITO006	LITO007	LITO008	LITO009	LITO010
LITO011	LITO012	LITO013	LITO014	LITO015
LITO016	LITO017			

LISQ001	LISQ002	LISQ003	LISQ004	LISQ005
LISQ006	LISQ007	LISQ008		

2) Abutment Screw

LSTO001	LSTO002	LSTO003	LSTO004	LSTO005
LSTO006	LSTO007	LSTO008	LSTO009	LSTO010
LSTO011	LSTO012	LSTO013	LSTO014	LSTO015
LSTO016	LSTO017	LSTO018	LSTO019	LSTO020
LSTO021	LSTO022	LSTO023	LSTO024	LSTO025
LSTO026	LSTO027	LSTO028	LSTO029	LSTO030
LSTO031	LSTO032	LSTO033	LSTO034	LSTO035
LSTO036	LSTO037	LSTO038	LSTO039	LSTO040
LSTO041	LSTO042	LSTO043	LSTO044	LSTO045
LSTO046	LSTO047	LSTO048	LSTO049	LSTO050
LSTO051	LSTO052	LSTO053	LSTO054	LSTO055
LSTO056	LSTO057	LSTO058	LSTO059	LSTO060
LSTO061				

LSCR001	LSCR002	LSCR003	LSCR004

LSHE201	LSHE202	LSHE203	LSHE204	LSHE205
LSHE206	LSHE207	LSHE208	LSHE209	LSHE210
LSHE211	LSHE212	LSHE213	LSHE214	LSHE215
LSHE216	LSHE217	LSHE218	LSHE219	LSHE220

LSTO201	LSTO202	LSTO203	LSTO204	LSTO205
LSTO206	LSTO207	LSTO208	LSTO209	LSTO210
LSTO211	LSTO212	LSTO213	LSTO214	LSTO215

LSTO216	LSTO217	LSTO218	LSTO219	LSTO220
LSTO221	LSTO222	LSTO223	LSTO224	LSTO225
LSTO226	LSTO227	LSTO228		

LSCR201	LSCR202

LSHE301	LSHE302	LSHE303	LSHE304	LSHE305
LSHE306	LSHE307	LSHE308	LSHE309	LSHE310
LSHE311	LSHE312	LSHE313		

LSTO301	LSTO302	LSTO303	LSTO304	LSTO305
LSTO306	LSTO307	LSTO308	LSTO309	LSTO310
LSTO311	LSTO312	LSTO313	LSTO314	

LSSQ301	LSSQ302

LSHE401	LSHE402	LSHE403	LSHE404	LSHE405
LSHE406	LSHE407	LSHE408	LSHE409	LSHE410

LSTO401	LSTO402	LSTO403	LSTO404	LSTO405
LSTO406	LSTO407	LSTO408	LSTO409	LSTO410
LSTO411	LSTO412	LSTO413	LSTO414	LSTO415

LSHE501	LSHE502	LSHE503	LSHE504	LSHE505
LSHE506	LSHE507			

LSTO501	LSTO502	LSTO503	LSTO504	LSTO505
LSTO506	LSTO507	LSTO508	LSTO509	LSTO510
LSTO511	LSTO512	LSTO513	LSTO514	

LSSQ501

LSHE601	LSHE602

LSTO601	LSTO602	LSTO603	LSTO604	LSTO605
LSTO606	LSTO607	LSTO608		

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

LSSQ601

(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: Link Abutment

Model name: Total 636 models including LIHE001

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: