

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 Medical Device Regulation (EU) 2017/745 and with the EN ISO 13485.

Manufacturer	ARUM DENTISTRY Co., Ltd. 23, Gukjegwahak 11-ro, Yuseong-gu, Daejeon, 34002, Rep. of Korea Tel : +82-42-935-3644 Homepage : www.arumdentistry.com
Device Name	Lab Analog
Brand Name	Lab Analog
Intended Use	A device intended to be used as a copy of a dental implant, for a dental laboratory working model, to duplicate the location and restorative platform orientation of the final dental implant. It is not intended for intraoral use. It is a rod-like device made of titanium.
Classification	Class I (Regulation 2017/745 of the European Parliament and of the council, Annex VIII Rule 1)
Model Name	Total 181 models including AGSHS001 (Refer to the Annex II for more details)
GMDN Code	61642 [Dental implant analog]
MD Code	0401 [Non-active dental equipment and instruments]
Basic UDI-DI	88000557LAB3
Conformity	Annex II and III Regulation 2017/745 of the European Parliament
Assessment Route	and of the council
Applied Standards	Refer to the Annex I
EC Representative	MedNet EC-REP IIb GmbH (SRN No. DE-AR-000011192) Borkstrasse 10, 48163 Muenster, Germany



Place and Date : Daejeon 2022.06.30

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	Regulation 2017/745 of the European Parliament and of the council	5 April 2017 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 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
8	MEDDEV 2.12-1 Rev. 8	Guidelines on a medical device vigilance system
9	MEDDEV 2.12-2 Rev. 2	Post market clinical follow up
10	MEDDEV 2.4/1 Rev. 9	Guidelines relating to the application of the council directive 93/42/EEC on medical devices
11	MEDDEV 2.5/10	Guideline for Authorized Representatives
12	MEDDEV 2.7.1 Rev. 4	Evaluation of clinical data

Annex II. Model Name

1) Lab Analog

A device intended to be used as a copy of a dental implant, for a dental laboratory working model, to duplicate the location and restorative platform orientation of the final dental implant. It is not intended for intraoral use. It is a rod-like device made of titanium.

AGSH001	AGSH002	AGSH003	AGSH004	AGSH005	AGSH006
AGSH007	AGSH008	AGSH009	AGSH010	AGSH011	AGSH012
AGSH013	AGSH014	AGSH015	AGSH016	AGSH017	AGSH018
AGSH019	AGSH020	AGSH021	AGSH022	AGSH023	AGSH024
AGSH025	AGSH026	AGSH027	AGSH028	AGSH029	AGSH030
AGSH031	AGSH032	AGSH033	AGSH034	AGSH035	AGSH036
AGSH037	AGSH038	AGSH039	AGSH040	AGSH041	AGSH042
AGSH043	AGSH044	AGSH045	AGSH046	AGSH047	AGSH048
AGSH049	AGSH050				

AGDH001	AGDH002	AGDH003	AGDH004	AGDH005	AGDH006
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AGIH001	AGIH002	AGIH003	AGIH004	AGIH005	AGIH006
AGIH007	AGIH008	AGIH009	AGIH010	AGIH011	AGIH012
AGIH013	AGIH014	AGIH015	AGIH016	AGIH017	AGIH018
AGIH019	AGIH020	AGIH021	AGIH022	AGIH023	AGIH024

AGHH001

AGSS001	AGSS002	AGSS003	AGSS004	AGSS005	AGSS006
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AGIO001	AGIO002	AGIO003	AGIO004	AGIO005	AGIO006
AGIO007	AGIO008	AGIO009	AGIO010	AGIO011	

AGSO001	AGSO002
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AGEO001

AGEH001	AGEH002	AGEH003	AGEH004	AGEH005	AGEH006
AGEH007	AGEH008	AGEH009	AGEH010	AGEH011	AGEH012
AGEH013	AGEH014	AGEH015	AGEH016	AGEH017	AGEH018

AGNH001	AGNH002	AGNH003	AGNH004	AGNH005	AGNH006
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AGNH007	AGNH008	AGNH009	AGNH010	AGNH011
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AGST001	AGST002	AGST003	AGST004	AGST005	AGST006
AGST007	AGST008	AGST009	AGST010	AGST011	AGST012
AGST013	AGST014	AGST015	AGST016		

AGIT001	AGIT002	AGIT003	AGIT004	AGIT005
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AGTT001	AGTT002	AGTT003	AGTT004	AGTT005	AGTT006
AGTT007	AGTT008	AGTT009			

AGSR001	AGSR002	AGSR003	AGSR004	AGSR005	AGSR006
AGSR007	AGSR008				

AGET001

AGSN001	AGSN002	AGSN003
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AEND001	AEND002
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AESP001	AESP002	AESP003
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AESQ001	AESQ002	AESQ003	AESQ004
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