

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 Screw
Brand Name	Lab Screw
Intended Use	A device intended to be used as a copy of a dental implant prosthetic screw to attach a dental implant abutment or prosthesis (e.g., crown, bridge) to a dental implant analog in a dental laboratory working model.
Classification	Class I (Regulation 2017/745 of the European Parliament and of the council, Annex VIII Rule 1)
Model Name	Total 304 models including SCSHE001 (Refer to the Annex II for more details)
GMDN Code	64312 [Dental prosthesis/implant abutment screw analog, single-use]
MD Code	0401 [Non-active dental equipment and instruments]
Basic UDI-DI	88000557LSC7
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 Screw

A device intended to be used as a copy of a dental implant prosthetic screw to attach a dental implant abutment or prosthesis (e.g., crown, bridge) to a dental implant analog in a dental laboratory working model.

SCSHE001	SCSHE002	SCSHE003	SCSHE004	SCSHE005	SCSHE006
SCSHE007	SCSHE008	SCSHE009	SCSHE010	SCSHE011	SCSHE012
SCSHE013	SCSHE014	SCSHE015	SCSHE016	SCSHE017	SCSHE018
SCSHE019	SCSHE020	SCSHE021	SCSHE022	SCSHE023	SCSHE024
SCSHE025	SCSHE026	SCSHE027	SCSHE028	SCSHE029	SCSHE030
SCSHE031	SCSHE032	SCSHE033	SCSHE034	SCSHE035	SCSHE036
SCSHE037	SCSHE038	SCSHE039	SCSHE040	SCSHE041	SCSHE042
SCSHE043	SCSHE044	SCSHE045	SCSHE047	SCSHE048	SCSHE049
SCSHE050	SCSHE051	SCSHE052	SCSHE053	SCSHE054	SCSHE055
SCSHE056	SCSHE057	SCSHE058	SCSHE059	SCSHE060	SCSHE061
SCSHE062	SCSHE063	SCSHE201	SCSHE202	SCSHE203	SCSHE204
SCSHE205	SCSHE206	SCSHE207	SCSHE208	SCSHE301	SCSHE302
SCSHE303	SCSHE304	SCSHE305	SCSHE306	SCSHE308	SCSHE309
SCSHE310	SCSHE311	SCSHE404	SCSHE405	SCSHE406	SCSHE503
SCSHE504	SCSHE505	SCSHE506	SCSHE601	SCSHE701	SCSHE702
SCSHE703	SCSHE704	SCSHE705	SCSHE706	SCSHE707	SCSHE708
SCSHE709	SCSHE710	SCSHE711	SCSHE712	SCSHE713	SCSHE714
SCSHE715	SCSHE716	SCSHE717	SCSHE718	SCSHE719	SCSHE720
SCSHE721	SCSHE722	SCSHE723	SCSHE724	SCSHE725	SCSHE726
SCSHE727	SCSHE728	SCSHE729	SCSHE730	SCSHE731	SCSHE732
SCSHE733	SCSHE734	SCSHE735	SCSHE736	SCSHE737	SCSHE738
SCSHE739	SCSHE740	SCSHE741	SCSHE742	SCSHE743	SCSHE744
SCSHE745	SCSHE746	SCSHE747	SCSHE748	SCSHE749	SCSHE750
SCSHE751	SCSHE752	SCSHE753	SCSHE754	SCSHE755	SCSHE756
SCSHE757	SCSHE758	SCSHE759			

SCSTO001	SCSTO002	SCSTO003	SCSTO005	SCSTO006	SCSTO007
SCSTO008	SCSTO009	SCSTO010	SCSTO201	SCSTO202	SCSTO203
SCSTO204	SCSTO301	SCSTO302	SCSTO401	SCSTO402	SCSTO602
SCSTO603	SCSTO604	SCSTO605	SCSTO606	SCSTO701	SCSTO702
SCSTO703	SCSTO704	SCSTO705	SCSTO706	SCSTO707	SCSTO708
SCSTO709	SCSTO710	SCSTO711	SCSTO712	SCSTO713	SCSTO714



SCSTO715	SCSTO716	SCSTO717	SCSTO718	SCSTO719	SCSTO720
SCSTO721	SCSTO722	SCSTO723	SCSTO724	SCSTO725	SCSTO726
SCSTO727	SCSTO728	SCSTO729	SCSTO730	SCSTO731	SCSTO732
SCSTO733	SCSTO734	SCSTO735	SCSTO736	SCSTO737	SCSTO738
SCSTO739	SCSTO740	SCSTO741	SCSTO742	SCSTO743	SCSTO745
SCSTO746	SCSTO747	SCSTO748	SCSTO749	SCSTO750	SCSTO751
SCSTO752	SCSTO753	SCSTO754	SCSTO755	SCSTO756	SCSTO757
SCSTO758	SCSTO759	SCSTO760	SCSTO761	SCSTO762	SCSTO763
SCSTO764	SCSTO765	SCSTO766	SCSTO767	SCSTO768	SCSTO769
SCSTO770	SCSTO771	SCSTO772	SCSTO773	SCSTO774	SCSTO775
SCSTO776	SCSTO777	SCSTO778	SCSTO779	SCSTO780	SCSTO781
SCSTO782	SCSTO783	SCSTO784	SCSTO785	SCSTO786	SCSTO787
SCSTO788	SCSTO789	SCSTO790	SCSTO791	SCSTO792	SCSTO793
SCSTO794	SCSTO795	SCSTO796	SCSTO797	SCSTO798	SCSTO799
SCSTO800	SCSTO801	SCSTO802	SCSTO803	SCSTO804	SCSTO805
SCSTO806	SCSTO807	SCSTO808	SCSTO809	SCSTO810	SCSTO811
SCSTO812	SCSTO813	SCSTO814	SCSTO815	SCSTO816	SCSTO817
SCSTO818	SCSTO819	SCSTO820	SCSTO821	SCSTO822	SCSTO823
SCSTO824	SCSTO825	SCSTO826	SCSTO827	SCSTO828	SCSTO829
SCSTO830					

SCSCR001	SCSCR002
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SCSSQ301	SCSSQ302	SCSSQ501
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SCSBL001
