

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	Model Scanbody
Brand Name	Model Scanbody
Intended Use	For obtain geometric data from the master model using a desktop laboratory 3D scanner or for optical impressions using intraoral 3D scanner.
Classification	Class I (Regulation 2017/745 of the European Parliament and of the council, Annex VIII Rule 1)
Model Name	Total 231 models including ASHS003 (Refer to the Annex II for more details)
GMDN Code	61641 [Dental implant abutment analog, scanning]
MD Code	0401 [Non-active dental equipment and instruments]
Basic UDI-DI	88000557MSBY5
Conformity	Annex II and III Regulation 2017/745 of the European Parliament and of the council
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) Model Scanbody

A non-sterile device intended to be used as temporary copy of a dental implant abutment in a patient to confirm the position of the final dental implant body during dental implant restorative procedures. It consists of a rod-like device intended to be attached to a dental implant.

(1) Submerged Hex: ASHS003 ~ ASHS069

ASHS003	ASHS005	ASHS006	ASHS007	ASHS009	ASHS010
ASHS011	ASHS012	ASHS013	ASHS014	ASHS015	ASHS016
ASHS019	ASHS020	ASHS021	ASHS022	ASHS023	ASHS024
ASHS025	ASHS027	ASHS028	ASHS029	ASHS030	ASHS031
ASHS032	ASHS033	ASHS034	ASHS035	ASHS036	ASHS038
ASHS039	ASHS040	ASHS041	ASHS042	ASHS043	ASHS044
ASHS045	ASHS047	ASHS048	ASHS049	ASHS050	ASHS051
ASHS052	ASHS053	ASHS054	ASHS055	ASHS056	ASHS057
ASHS058	ASHS059	ASHS060	ASHS061	ASHS062	ASHS063
ASHS064	ASHS065	ASHS066	ASHS067	ASHS068	ASHS069

(2) Hex: AHES001 ~ AHES028

AHES001	AHES002	AHES003	AHES004	AHES005	AHES006
AHES007	AHES008	AHES009	AHES010	AHES011	AHES012
AHES013	AHES014	AHES015	AHES016	AHES017	AHES018
AHES019	AHES020	AHES021	AHES022	AHES023	AHES024
AHES025	AHES026	AHES027	AHES028		

(3) Non-Hex: ANHS001 ~ ANHS004

ANHS001	ANHS002	ANHS003	ANHS004
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(4) Square: ASQS001 ~ ASQS011

ASQS001	ASQS002	ASQS003	ASQS004	ASQS005	ASQS006
ASQS007	ASQS008	ASQS009	ASQS010	ASQS011	

(5) Octa: AOCS001 ~ AOCS019

AOCS001	AOCS002	AOCS003	AOCS004	AOCS005	AOCS006
AOCS007	AOCS009	AOCS010	AOCS012	AOCS013	AOCS015
AOCS016	AOCS017	AOCS018	AOCS019		

(6) External Octa: ANEO001

ANEO001

(7) External Hex: AEXS001 ~ AEXS017

AEXS001	AEXS002	AEXS003	AEXS004	AEXS008	AEXS011
AEXS012	AEXS013	AEXS016	AEXS017		

(8) External Non-Hex: AENS001 ~ AENS048

AENS001	AENS002	AENS003	AENS004	AENS005	AENS006
AENS008	AENS009	AENS011	AENS012	AENS013	AENS014
AENS015	AENS016	AENS017	AENS018	AENS019	AENS020
AENS021	AENS023	AENS024	AENS025	AENS026	AENS027
AENS028	AENS029	AENS030	AENS031	AENS032	AENS034
AENS035	AENS036	AENS037	AENS038	AENS039	AENS040
AENS041	AENS042	AENS043	AENS044	AENS045	AENS046
AENS047	AENS048				

(9) Torx: ATXS001 ~ ATXS018

ATXS001	ATXS002	ATXS003	ATXS004	ATXS005	ATXS006
ATXS007	ATXS008	ATXS009	ATXS010	ATXS011	ATXS012
ATXS013	ATXS014	ATXS015	ATXS016	ATXS017	ATXS018

ATRS001	ATRS002	ATRS003	ATRS004	ATRS005	ATRS006
ATRS007	ATRS008	ATRS009	ATRS010	ATRS011	ATRS012
ATRS013	ATRS014	ATRS015	ATRS016	ATRS017	ATRS018
ATRS019					

AETS001

APRS001	APRS002
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ASTS001	ASTS002	ASTS003
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2) Model Scanbody Screw

Use the scan body screw to attach the scan body to the implant, tightening the screw to hold.

AHHS001	AHHS004	AHHS008	AHHS010	AHHS014	AHHS016
AHHS017	AHHS018	AHHS019	AHHS020	CSHE501	AHHS021
AHHS022	AHHS023				