



ARUM DENTISTRY Co., Ltd.

1-dong, 44, Techno 8-ro, Yuseong-gu, Daejeon, Korea

## EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Product Name: Intraoral Scan Body

Model Name : Total 358 models including B4SH001  
(See Annex 1 for more details)

Brand Name : ARUM PLANT SB II

Classification : Class I (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 1)

Conformity Assessment Route : Annex VII, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

Applied Standards : EN ISO 13485:2016, EN ISO 14971:2012, EN ISO10993-1:2009/ AC:2010, ISO 10993-5:2009, ISO10993-10:2010, EN ISO 10993-11:2009, EN1041:2008, ISO15223-1:2016, EN ISO 11607-1:2009, ISO 14801:2007, ISO14644-1:1999, ISO14644-2:2000, MEDDEV 2.7.1/Rev.4

Manufacturers Registered Name : ARUM DENTISTRY Co., Ltd.

EC Representative : MedNet EC-REP GmbH  
Borkstrasse 10, 48163 Muenster,. Germany

GMDN Code No. : 61641



Signature :

  
Jeon Byeong Woo / President

Date: 2020.04.30

# Annex 1

## 1) Intraoral Scan Body

B4SH001	B4SH002	B4SH003	B4SH004	B4SH005	B4SH006
B4SH007	B4SH008	B4SH009	B4SH010	B4SH011	B4SH012
B4SH013	B4SH014	B4SH015	B4SH016	B4SH017	B4SH018
B4SH019	B4SH020	B4SH021	B4SH022	B4SH023	B4SH024
B4SH025	B4SH026	B4SH027	B4SH028	B4SH029	B4SH030
B4SH031	B4SH032	B4SH033	B4SH034	B4SH035	B4SH036
B4SH037	B4SH038	B4SH039	B4SH040	B5SH001	B5SH002
B5SH003	B5SH004	B5SH005	B5SH006	B5SH007	B5SH008
B5SH009	B5SH010	B5SH011	B5SH012	B5SH013	B5SH014
B5SH015	B5SH016	B5SH017	B5SH018	B5SH019	B5SH020
B5SH021	B5SH022	B5SH023	B5SH024	B5SH025	B5SH026
B5SH027	B5SH028	B5SH029	B5SH030	B5SH031	B5SH032
B5SH033	B5SH034	B5SH035	B5SH036	B5SH037	B5SH038
B5SH039	B5SH040	B5SH041	B5SH042	B5SH043	B5SH044
B6SH001	B6SH002	B6SH003	B6SH004	B6SH005	B6SH006
B6SH007	B6SH008	B6SH009	B6SH010	B6SH011	B6SH012
B6SH013	B6SH014	B6SH015	B6SH016	B6SH017	B6SH018
B6SH019	B6SH020	B6SH021	B6SH022	B6SH023	B6SH024
B6SH025	B6SH026	B6SH027	B6SH028	B6SH029	B6SH030
B6SH031	B6SH032	B6SH033	B6SH034	B6SH035	B6SH036
B6SH037	B6SH038	B6SH039	B6SH040	B6SH041	B6SH042
B6SH043	B6SH044	B6SH045	B6SH046	B6SH047	B6SH048
B4EH001	B4EH002	B4EH003	B4EH004	B4EH005	B4EH006
B4EH007	B4EH008	B4EH009	B4EH010	B4EH011	B4EH012
B4EH013	B4EH014	B5EH001	B5EH002	B5EH003	B5EH004
B5EH005	B5EH006	B5EH007	B5EH008	B5EH009	B5EH010
B5EH011	B5EH012	B5EH013	B5EH014	B5EH015	B5EH016
B5EH017	B5EH018	B5EH019	B5EH020	B5EH021	B5EH022
B6EH001	B6EH002	B6EH003	B6EH004	B6EH005	B6EH006
B6EH007	B6EH008	B6EH009	B6EH010	B6EH011	B6EH012
B6EH013	B6EH014	B6EH015	B6EH016	B6EH017	B6EH018
B6EH019	B6EH020	B6EH021	B6EH022	B6EH023	B6EH024
B4IT001	B4IT002	B4IT003	B4IT004	B4IT005	B4IT006
B4IT007	B4IT008	B5IT001	B5IT002	B5IT003	B5IT004
B5IT005	B5IT006	B5IT007	B5IT008	B5IT009	B5IT010
B5IT011	B5IT012	B6IT001	B6IT002	B6IT003	B6IT004
B6IT005	B6IT006	B6IT009	B6IT010	B6IT011	B6IT012
B6IT013	B6IT014	B6IT015	B6IT016	B4IO001	B4IO002
B4IO003	B4IO004	B4IO005	B4IO006	B5IO001	B5IO002
B5IO003	B5IO004	B5IO005	B5IO006	B5IO007	B5IO008
B5IO009	B5IO010	B5IO011	B5IO012	B6IO001	B6IO002
B6IO003	B6IO004	B6IO005	B6IO006	B6IO007	B6IO008
B6IO009	B6IO010	B6IO011	B6IO012	B4IS001	B4IS002
B4IS003	B4IS004	B5IS001	B5IS002	B5IS003	B5IS004
B6IS001	B6IS002	B6IS003	B6IS004	OSHE001	OSHE002
OSHE003	OSHE004	OSHE005	OSHE006	OSHE007	OSHE008
OSHE009	OSHE010	OSHE011	OSHE012	OSHE013	OSHE014
OSHE015	OSHE016	OSHE017	OSHE018	OSHE019	OSHE020
OSHE021	OSHE022	OSHE023	OSHE024	OSHE025	OSHE026
OSHE027	OSHE028	OSHE029	OSHE030	OSHE031	OSHE032
OSHE033	OSHE034	OSHE035	OSHE036	OSSQ001	OSSQ002
OSSQ003	OSSQ004	OSSQ005	OSSQ006		

## 2) Intraoral Scan Body Screw

BHES001	BHES002	BHES003	BHES004	BHES005	BHES006
BHES007	BHES008	BHES009	BHES010	BHES011	BHES012
BHES013	BHES014	BHES015	BHES016	BHES017	BHES018
BHES019	BHES020	BHES021	BHES022	BHES023	BHES024
OSSH001	OSSH002	OSSH003	OSSH004	OSSH005	OSSH006
OSSH007	OSSH008	OSSH009	OSSH010	OSSH011	OSSH012
OSSH013	OSSH014	OSSH015	OSSH016	OSST001	OSST002
OSST003	OSST004	OSST005	OSST006		

## 3) JIG(accessory)

IOJI008	IOJI010				
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