ARUM DENTISTRY Co., Ltd.

1-dong, 44, Techno 8-ro, Yuseong-gu, Daejeon, 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. All supporting documentation is retained under the premises of the manufacturer.

Manufacturer	ARUM DENTISTRY Co., Ltd. 1-dong, 44, Techno 8-ro, Yuseong-gu, Daejeon, Korea Tel : +82-42-935-3644 Homepage : www.arumdentistry.com
Trade Name	ARUM Screw Driver
Intended Use	Screw Driver is that to tighten screws in the process of combining artificial dental punch work or implant components.
Classification	Class I (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 1)
Model Name	Total 40 models including BDHE008 (Refer to the Annex II for more details)
GMDN Code	33968 [Surgical Screwdriver, reusable]
Conformity Assessment Route	Annex VII Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC
Applied Standards	Refer to the Annex I.
EC Representative	MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany

CE

Place and date : Daejeon 2021.05.20 **Signature :** **LEE Jeong Hyun / CEO**

Annex I. Applied Standards

No.	Standard	Standard Name
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	93/42/EEC amended by Directive 2007/47/EC	5 September 2007 concerning medical devices
3	EN 1041:2008	Information supplied by the manufacturer with medical devices
4	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
5	ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
6	ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
7	ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
8	ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for skin sensitization
9	MEDDEV 2.12-1 Rev. 8	Guidelines on a medical device vigilance system
10	MEDDEV 2.12-2 Rev. 2	Post market clinical follow up
11	MEDDEV 2.4/1 Rev. 9	Guidelines relating to the application of the council directive 93/42/EEC on medical devices
12	MEDDEV 2.5/10	Guideline for Authorized Representatives
13	MEDDEV 2.7.1 Rev. 4	Evaluation of clinical data

Annex II. Model Name

1) Clinical Ball Screw Driver

BDHE008	BDHE015	BDHE022

BDTO008	BDTO015	BDTO022

2) Clinical Tip Screw Driver

BHD12H

BTD17H

3) Lab Screw Driver

LDH100L	LDH120L	LDH125L	LDH127L	LDH130L	LBH120L
IDH100L	IDH120L	IDH125L	IDH127L	IDH130L	IBH120L
IDM1430	IDM1635	IDM1835	IDM2040	IDM2540	

LDT160L	LDT170L	LBT170L	LDT150L	IDT150L	IDT170L
IBT170L					

LDC127L	ICT125L

4) Driver Handle (Accessory)

LHOR	LHBL	LHGO	IPENH

5) End Cover (Accessory)

LBEC	IHEC

(주)아름덴티스트리 ARUM DENTISTRY Co., Ltd.
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Declaration of Conformity (DoC) Corrigendum

Product name : ARUM Screw Driver

Brand name : ARUM Screw Driver

Model name : Total 40 models including BDHE008

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

Date of the DoC : 2021.05.20

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. Therefore, we should be correction of the information in previous DoC.

Name : Jeong Hyeon Lee

Position : CEO

Place and Date : Daejeon 2022.06.20

Signature :