DOOWON

DW-2016-3

EC Declaration of Conformity

Manufacturers Registered Name : DOOWONID Co., Ltd.
1-dong, 44, Techno 8-ro, Yuseong-gu, Daejeon, Korea
Tel: +82-42-721-3644

EC Representative : MedNet GmbH
Borkstrasse 10, 48163 Muenster, Germany
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Declares that the product

Brand Name : ARUM PLANT SCREW Ⅰ

Device Name : Lab Screw

Model Name : Total 147 models including SCSHE001

GMDN Code : 61646 (Dental implant prosthetic screw analog)

Relevant EC Directives : Medical Device Directive 93/42/EEC amended by 2007/47/EC

Classification : Class I (Rule 1)

Conformity Assessment Route : Annex Ⅶ

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

In conformity with the national standard transposing harmonized standards ; See Attachment

Date : 2016. 12. 05

Doo Hyun Baek

Doo-hyun Baek / *C.E.O*

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[List of Harmonized Standards]

No.	Category	Title	Description
1	System	Directive 2007/47/EC	of 5 September 2007 concerning medical devices
		EN ISO 14971 : 2012	Medical devices - Application of risk management to medical devices
		MEDDEV2.12-1 Rev.8	Guidelines on a medical device vigilance system
2	ETC	MEDDEV2.4/1 Rev.9 June 2010	Guidelines relating to the application of the council directive 93/42/EEC on medical devices
		ISO 15223-1 : 2012	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
		EN 1041: 2008	Information supplied by the manufacturer with medical devices
3	Clinical investigation	ISO14155 : 2011	Clinical investigation of medical devices for human subjects – Good clinical practice
		MEDDEV2.7.1 Rev.3 December 2009	Evaluation of clinical data
		MEDDEV2.12-2 Rev.2 January 2012	Post market clinical follow up