HUBIT

CE 2195

EC DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

This Declaration of Conformity is only valid with record of final inspection for a specific lot./device enclosed.

MANUFACTURER:	**HUBIT Co., Ltd.** (Ojeon-dong, Byeoksantechnopia), A-1204, 13 Ojeongongeop-gil, Uiwang-si, Gyeonggi-do, Korea TEL. +82-31-477-9902
EUROPEAN REPRESENTATIVE:	**SC ORTOFORUM SRL** 224 ANDREI SAGUNA STREET , 310077 ARAD, ROMANIA TEL. +40 257 251 715 FAX. +40 257 251 715
PRODUCT (Model/type):	Orthodontic Mini Screw (MINI SCREW) *Refer to the Attachment #1.*
CLASSIFICATION:	Ⅱb
RULE TO BE APPLIED:	8
CONFORMITY ASSESSMENT ROUT:	Annex Ⅱ (excluding Section 4) (Full Quality Assurance System)

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	*Refer to the Attachment #2.*
NOTIFIED BODY:	Notified Body Number 2195, Szutest Teknik Kontrol ve Belgelendirme Hizmetleri Ticaret Limited Şirketi Yukarı Dudullu Mahallesi Nato Yolu Caddesi Çam Sokak No: 7 Ümraniye/İSTANBUL, Turkey
(EC) CERTIFICATE(S):	*2195-MED-1306401* *(Issue date:2013.05.31, Valid date:2018.03.04)*
GMDN Code:	*46536*
PLACE:	In Uiwang-si,
SIGNATURE:	Hag-Dong Yoo / President

Attachment #1.

Size(mm)	Standard Type	Cross Head Type
1.4*6L	OA1206	
1.4*8L	OA1208	
1.6*6L	OA1506	OC1406
1.6*8L	OA1508	OC1408
1.6*10L	OA1510	OC1410
1.8*6L	OA1606	OC1606
1.8*8L	OA1608	OC1608
1.8*10L	OA1610	OC1610
1.5*6L	OS1206	
1.5*8L	OS1208	
1.7*6L	OS1406	
1.7*8L	OS1408	
1.7*10L	OS1410	
1.9*6L	OS1606	
1.9*8L	OS1608	
1.9*10L	OS1610	
2.0*6L		OC1806
2.0*8L		OC1808
2.0*10L		OC1810

Attachment #2.

European Norms and Standards and other Documents supporting Technical Files;

EN ISO 15223-1:2008, Symbols for use in the labeling of medical devices

EN 1041:2008, Information supplied by the manufacturer of medical devices

EN 1641:2009, Dentistry - Medical devices for dentistry – Materials

EN ISO 5832-2:2012, Implants for surgery – Metallic materials – Part 2: Unalloyed titanium

EN ISO 7405:2008, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

EN ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing

EN ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity

EN ISO 10993-11:2009, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

EN ISO 13485:2012, Medical Devices – Quality Management Systems for Regulatory Purpose

EN ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice

EN ISO 14971:2012, Medical devices – Application of risk management to medical devices

ASTM F 136-02a (2002), Standard Specification for Wrought Titaniump-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

KFDA Notification No. 2011-59, Common standards for Biological safety of Medical Devices Part 5. Tests for in vitro cytotoxicity

KFDA Notification No. 2011-58, Common standards for Biological safety of

Medical Devices Part 3 & 9. Tests for irritation and delayed-type hypersensitivity

MEDDEV 2.7.1 Rev.3: Guidelines on Medical Devices Clinical Evaluation

MEDDEV 2.12.1 Rev.8: Guidelines on Medical Devices Vigilance System

MEDDEV 2.12.2 Rev.2: Guidelines on Post Market Clinical Follow-up Studies, Medical devices –Application of risk management to medical devices