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 Wire (PERFECT/Gemma/MTA wire) *Refer to the Attachment #1 for type numbers.*
CLASSIFICATION:	Ⅱa
RULE TO BE APPLIED:	5
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:	*16204*
PLACE:	In Uiwang-si,
SIGNATURE:	Hag-Dong Yoo / President 22.01.2014

Attachment #1.

a) PERFECT

Form	Wire Size (In.)	S.S		Ni-Ti		Approved for Sale in
		Upper	Lower	Upper	Lower	
Round (Ø)	.012	701-10	701-20	701-11	701-21	Korea
	.014	702-10	702-20	702-11	702-21	Korea
	.016	703-10	703-20	703-11	703-21	Korea
	.018	704-10	704-20	704-11	704-21	Korea
	.020	705-10	705-20	705-11	705-21	Korea
Rectangular (h × b)	.016 × .016	706-10	706-20	706-11	706-21	Korea
	.016 × .022	707-10	707-20	707-11	707-21	Korea
	.017 × .022	708-10	708-20	708-11	708-21	Korea
	.017 × .025	709-10	709-20	709-11	709-21	Korea
	.018 × .025	710-10	710-20	710-11	710-21	Korea
	.019 × .025	711-10	711-20	711-11	711-21	Korea
	.021 × .025	712-10	712-20	707-12	712-21	Korea

b) Gemma

Form	Wire Size (In.)	Ni-Ti		S.S		Approved for Sale in
		Upper	Lower	Upper	Lower	
Round (Ø)	.012	760-01	760-02	761-01	761-02	Korea
	.014	760-03	760-04	761-03	761-04	Korea
	.016	760-05	760-06	761-05	761-06	Korea
	.018	760-07	760-08	761-07	761-08	Korea
	.020	760-09	760-10	761-09	761-10	Korea
Rectangular (h × b)	.016 × .016	760-11	760-12	761-11	761-12	Korea
	.016 × .022	760-13	760-14	761-13	761-14	Korea
	.017 × .022	760-15	760-16	761-15	761-16	Korea
	.017 × .025	760-17	760-18	761-17	761-18	Korea
	.018 × .025	760-19	760-20	761-19	761-20	Korea
	.019 × .025	760-21	760-22	761-21	761-22	Korea
	.021 × .025	760-23	760-24	761-23	761-24	Korea

c) MTA WIRE

MTA wire	Parts number
012 NiTi	750-01
014 NiTi	750-02
35°C thermo-active 012 NiTi	751-01
35°C thermo-active 014 NiTi	751-02
40°C thermo-active 012 NiTi	752-01
40°C thermo-active 014 NiTi	752-02
45°C thermo-active 012 NiTi	753-01
45°C thermo-active 014 NiTi	753-02

Attachment #2.

European Norms and Standards and other Documents supporting Technical Files;

EN ISO 15223-1:2012, 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 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/AC:2012, Medical Devices – Quality Management Systems for Regulatory Purpose

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

EN ISO 15841:2006, Dentistry – Wires for use in orthodontics

EN ISO 22674:2006, Dentistry. Metallic materials for fixed and removable restorations and appliances

USP 30 NF 25 <87> Biological Reactivity Tests, In Vitro Elution Test

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