

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.
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224 ANDREI SAGUNA STREET ,
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PRODUCT (Model/type): Orthodontic Tube (SM TUBE)
Refer to the Attachment #1.

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
2195-MED-1306401
(Issue date: 05/03/2013, Valid date: 04/03/2018)

(EC) CERTIFICATE(S):

GMDN Code: 31759

PLACE: In Uiwang-si,

SIGNATURE: 
Hag-Dong Yoo /
President

Attachment #1.

a) SINGLE Type

1) ROTH - BONDABLE TUBE

Tooth		Torque	Offset	Angle	Parts number			
					.018 Slot		.022 Slot	
					R	L	R	L
Maxillary	1st Molars	-10°	7°	0°	500-16	500-26	510-16	510-26
	2nd Molars	-14°	9°	0°	500-17	500-27	510-17	510-27
Mandibular	1st Molars	-20°	4°	0°	500-46	500-36	510-46	510-36
	2nd Molars	-25°	6°	0°	500-47	500-37	510-47	510-37

2) ROTH - WELDABLE TUBE

Tooth		Torque	Offset	Angle	Parts number			
					.018 Slot		.022 Slot	
					R	L	R	L
Maxillary	1st Molars	-10°	7°	0°	501-16	501-26	511-16	511-26
	2nd Molars	-14°	9°	0°	501-17	501-27	511-17	511-27
Mandibular	1st Molars	-20°	4°	0°	501-46	501-36	511-46	511-36
	2nd Molars	-25°	6°	0°	501-47	501-37	511-47	511-37

3) MBT - BONDABLE TUBE

Tooth		Torque	Offset	Angle	Parts number			
					.018 Slot		.022 Slot	
					R	L	R	L
Maxillary	1st Molars	-14°	10°	0°			530-16	530-26
	2nd Molars	-14°	10°	0°			530-17	530-27
Mandibular	1st Molars	-20°	0°	0°			530-46	530-36
	2nd Molars	-10°	0°	0°			530-47	530-37

4) MBT - WELDABLE TUBE

Tooth		Torque	Offset	Angle	Parts number			
					.018 Slot		.022 Slot	
					R	L	R	L
Maxillary	1st Molars	-14°	10°	0°			531-16	531-26
	2nd Molars	-14°	10°	0°			531-17	531-27
Mandibular	1st Molars	-20°	0°	0°			531-46	531-36
	2nd Molars	-10°	0°	0°			531-47	531-37

5) STANDARD - BONDABLE TUBE

Tooth		Torque	Offset	Angle	Parts number			
					.018 Slot		.022 Slot	
					R	L	R	L
Maxillary	1st Molars	0°	0°	0°	540-16	540-26	550-16	550-26
	2nd Molars							
Mandibular	1st Molars							
	2nd Molars							

Attachment #2.

b) TWIN type

1) ROTH - BONDABLE TUBE

Tooth		Torque	Offset	Angle	M/D width	Parts number			
						.018 Slot		.022 Slot	
						R	L	R	L
Maxillary	1st Molars	-10 ^o	7 ^o	0 ^o		502-16	502-26	512-16	512-26
	2nd Molars	-14 ^o	9 ^o	0 ^o		502-17	502-27	512-17	512-27
Mandibular	1st Molars	-20 ^o	4 ^o	0 ^o		502-46	502-36	512-46	512-36
	2nd Molars	-25 ^o	6 ^o	0 ^o		502-47	502-37	512-47	512-37

2) ROTH - WELDABLE TUBE

Tooth		Torque	Offset	Angle	M/D width	Parts number			
						.018 Slot		.022 Slot	
						R	L	R	L
Maxillary	1st Molars	-10 ^o	7 ^o	0 ^o		503-16	503-26	513-16	513-26
	2nd Molars	-14 ^o	9 ^o	0 ^o		503-17	503-27	513-17	513-27
Mandibular	1st Molars	-20 ^o	4 ^o	0 ^o		503-46	503-36	513-46	513-36
	2nd Molars	-25 ^o	6 ^o	0 ^o		503-47	503-37	513-47	513-37

3) MBT - BONDABLE TUBE

Tooth		Torque	Offset	Angle	M/D width	Parts number			
						.018 Slot		.022 Slot	
						R	L	R	L
Maxillary	1st Molars	-14 ^o	10 ^o	0 ^o				532-16	532-26
	2nd Molars	-14 ^o	10 ^o	0 ^o				532-17	532-27
Mandibular	1st Molars	-20 ^o	0 ^o	0 ^o				532-46	532-36
	2nd Molars	-10 ^o	0 ^o	0 ^o				532-47	532-37

4) MBT - WELDABLE TUBE

Tooth		Torque	Offset	Angle	M/D width	Parts number			
						.018 Slot		.022 Slot	
						R	L	R	L
Maxillary	1st Molars	-14 ^o	10 ^o	0 ^o				533-16	533-26
	2nd Molars	-14 ^o	10 ^o	0 ^o				533-17	533-27
Mandibular	1st Molars	-20 ^o	0 ^o	0 ^o				533-46	533-36
	2nd Molars	-10 ^o	0 ^o	0 ^o				533-47	533-37

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 10993-1:2009/AC:2010, 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 13485:2012/AC:2012, Medical Devices – Quality Management Systems for Regulatory Purpose

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

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

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

EN ISO 27020:2010, Dentistry – Brackets and tubes for use in orthodontics

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