

## 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 Bracket (WOW Advanced)  
*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:2013.05.31, Valid date:2018.03.04)

**(EC) CERTIFICATE(S):**

**GMDN Code:** 46581

**PLACE:** In Uiwang-si,

**SIGNATURE:**   
Hag-Dong Yoo /  
President



<i>Anteriors</i>	-6°	0°	2.85	<b>124-41/42</b>	<b>124-31/32</b>	<b>134-41/42</b>	<b>134-31/32</b>	KOREA
<i>Cuspids</i>	0°	+3°	3.50	<b>124-43(H)</b>	<b>124-33(H)</b>	<b>134-43(H)</b>	<b>134-33(H)</b>	KOREA
<i>1<sup>st</sup>Bicuspids</i>	-12°	0°	3.20	<b>124-44(H)</b>	<b>124-34(H)</b>	<b>134-44(H)</b>	<b>134-34(H)</b>	KOREA
<i>2<sup>nd</sup>Bicuspids</i>	-12°	0°	3.20	<b>124-45(H)</b>	<b>124-35(H)</b>	<b>134-45(H)</b>	<b>134-35(H)</b>	KOREA

<b>ASSORTED KIT</b>		<b>.018 Slot</b>	<b>.022 Slot</b>
Lower 3-3, Without Hooks on Cuspids(31,32,33, 41,42,43)		<b>124-030</b>	<b>134-030</b>
Lower 3-3, Hooks on Cuspids(31,32,33H, 41,42,43H)		<b>124-031</b>	<b>134-031</b>
Upper 3-3, Without Hooks on Cuspids(11,12,13, 21,22,23)		<b>124-300</b>	<b>134-300</b>
Upper 3-3, Hooks on Cuspids(11,12,13H, 21,22,23H)		<b>124-301</b>	<b>134-301</b>
Upper and Lower 3-3, Without Hooks on Cuspids (11,12,13, 21,22,23, 31,32,33, 41,42,43)		<b>124-330</b>	<b>134-330</b>
Upper and Lower 3-3, Hooks on Cuspids (11,12,13H, 21,22,23H, 31,32,33H, 41,42,43H)		<b>124-331</b>	<b>134-331</b>
Lower 5-5, Without Hooks on Cuspids(31,32,33,34,35 41,42,43,44,45)		<b>124-050</b>	<b>134-050</b>
Lower 5-5, Hooks on Cuspids(31,32,33H,34,35 41,42,43H,44,45)		<b>124-051</b>	<b>134-051</b>
Lower 5-5, Hooks on #3,4,5 (31,32,33H,34H,35H 41,42,43H,44H,45H)		<b>124-053</b>	<b>134-053</b>
Upper 5-5, Without Hooks on Cuspids(11,12,13,14,15 21,22,23,24,25)		<b>124-500</b>	<b>134-500</b>
Upper 5-5, Hooks on Cuspids(11,12,13H,14,15 21,22,23H,24,25)		<b>124-501</b>	<b>134-501</b>
Upper 5-5, Hooks on #3,4,5 (11,12,13H,14H,15H 21,22,23H,24H,25H)		<b>124-503</b>	<b>134-503</b>
Upper and Lower 5-5, Without Hooks on Cuspids (11,12,13,14,15 21,22,23,24,25, 31,32,33,34,35 41,42,43,44,45)		<b>124-550</b>	<b>134-550</b>
Upper and Lower 5-5, Hooks on Cuspids (11,12,13H,14,15 21,22,23H,24,25, 31,32,33H,34,35 41,42,43H,44,45)		<b>124-551</b>	<b>134-551</b>
Upper and Lower 5-5, Hooks on #3,4,5 (11,12,13H,14H,15H,21,22,23H,24H,25H,31,32,33H,34H,35H,41,42,43H,44H,45H)		<b>124-553</b>	<b>134-553</b>

**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, 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, 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  
ASTM F1145-05, Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings  
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