

Declaration of Conformity

DENOVO

This EU declaration of conformity has been issued under the sole responsibility of Denovo Dental, inc.

Manufacturer:	European Representative:	Notified Body
DENOVO Dental Inc. SRN: <i>Not yet available</i> 5130 Commerce Dr Baldwin Park, CA 91706 T: (626) 939-5000 F: (626) 939-5020	KinderDent GmbH SRN: <i>Not yet available</i> Gutenbergstraße 7 D - 28844 Weyhe, Germany T: +49 (0) 4203 - 43 - 318 F: +49 (0) 4203 - 43 - 4 - 366	SZUTEST Uygunluk Degerlendirme A.S. CE #2195 SRN: <i>Not yet available</i> SZUTEST Plaza Yukan; Dudullu Mh. Nato Yolu; Umraniye – Istanbul – Turkiye T: +90 216 469 46 66 F: +90 216 469 46 67

Product & Trade Name:		
Space Maintainer System Stainless Steel Molar Bands Stainless Steel Crowns		
GMDN Codes:	Basic UDI-DI	
31754, 38734, 16204, 31759, 34976	Denovo Prefix: 081005929 Product GTIN: 081005929XXXX; See MDF for complete listing	
Risk Class:	Conformity Assessment Procedure:	Common Specifications:
Class IIa Annex VIII MDR 2017	Annex II of 93/42/EEC	<i>not applicable</i>
Catalogue Numbers:	Certification:	
160-XXX; 161-XXX; 38X-XXX; 930-XXX; 900-XXX; 902-XXX; 907-XXX; 8385-XXX; 8906-XXX. See MDF for complete listing	ISO 13485:2016 Cert. # 32229102 CE Cert # 2195-MED-1318401 Location: Baldwin Park, CA, USA	

We, the undersigned, hereby declare that the requirements specified in the applicable regulations and standards have been fulfilled and that the devices covered by the present declaration are in conformity with applicable regulation and with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. All supporting documents are retained at the premises of the distributor.



Joseph Parker
President



Phil Horton
Operations Manager



Charles Hanna,
Regulatory Manager

