

Declaration of Conformity

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

Manufacturer:	European Representative:	Notified Body
DENOVO Dental Inc.	KinderDent GmbH	SZUTEST Uygunluk Degerlendirme A.S.
SRN: Not yet available	SRN: Not yet available	CE #2195 SRN: Not yet available
5130 Commerce Dr Baldwin Park, CA 91706	Gutenbergstraße 7 D - 28844 Weyhe, Germany	SZUTEST Plaza Yukan; Dudullu Mh. Nato Yolu; Umraniye – Istanbul – Turrkiye
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Product & Trade Name:			18 miles
Pediatric Forceps; Dental Crown Instruments; Orthodontic Instruments; Dental Scissors; General Dental Instruments	3 3300		Julius de la constant
GMDN Code:	Basic UDI-DI		
16463, 31801, 31847, 32885, 33209, 35552, 35812, 37413	Denovo Prefix: 081005929 Product GTIN: 081005929XXXX; See MDF for complete listing		
Risk Class:	Conformity Assessment Procedure:		Common Specifications:
Class I Annex VIII MDR 2017 Annex II of 93/4		2/EEC	not applicable
Catalogue Numbers:		Certification:	
800-xxx, 801-xxx, 802-xxx, 805-xxx, 811-xxx, 813-xxx See MDF for complete listing		Cert # 2195-MED-1318401 Location: Baldwin Park, CA, USA Issued: 2013.07.03	

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

Phil Harlen

Charles Hanna Regulatory Manager

CE