

EC Declaration of Conformity

According to Annex II of Directive 93/42/EEC on Medical Devices
EN ISO 13485:2016 – ISO 13485:2003

DENOVO Dental Inc.

Baldwin Park, California, USA

Confirms that the products under the prefixes listed in this certificate complies fully with the applicable standards referenced.

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|--------------------------------|---|
| Manufacturer Information | DENOVO Dental Inc. 5130 Commerce Drive Baldwin Park, California 91706 |
| European Representative | KinderDent GmbH Gutenbergstraße 7 D - 28844 Weyhe, Germany Phone +49 (0) 4203 - 43 - 318 FAX +49 (0) 4203 - 43 - 4 - 366 |
| Product Name | Space Maintainers and accessories |
| Classification (MDD, Annex IX) | Class IIa – Rule 8 - 94/42/EEC Annex IX |
| Conformity Assessment Route | Annex II of 93/42/EEC |
| Standards Applied | EN ISO 13485:2016, ISO 14155:2011, EN 1641:2009, EN ISO 14971:2012, EN 980:2008, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 10993-11:2009. |
| Notified Body | SZUTEST Uygunluk Degerlendirme A.S. CE #2195 SZUTEST Plaza Yukan Dudullu Mh. Nato Yolu Umraniye – Istanbul - Turkiye Tel: +90 216 469 46 66 FAX: +90 216 469 46 67 |
| EC Certificate | Place Baldwin Park, CA Date of Issue 06/01/2013 Valid through 06/28/2021 Cert # 2195-MED-1318401 |
| Start of CE Marking | 2013.06.01 |
| Technical File Date of Issue: | 2012.08.09 |
| Place: | Baldwin Park, CA USA |
| Catalog Numbers | 16x-xxx, 387-xxx, 800-xxx, 801-xxx, 805-xxx, 811-xxx, 813-xxx, 900-xxx, 902-xxx, 907-xxx, 930-xxx, 190-xxx, MMS900-xxx, MS900-xxx, PB907-xxx, PBS907-xxx, B160-xxx See Product List for complete listing |
| GMDN Codes | 38734, 16204, 31759, 34976, 46338. |

We, the undersigned, hereby declare, under our sole responsibility, that the above-mentioned products conform to the specified Directives and Standards (93/42/EEC). All supporting documents are retained at the premises of the distributor.

Date: 2018.08.21



Phil Horton

Phil Horton, Service Manager

