

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-1318401

Manufacturer: DENOVO DENTAL Inc.
5130 Commerce Dr., Baldwin Park, CA 91706 USA

Product(s): Space Maintainer System Products

Model(s):
1. Stainless Steel Bands
2. Stainless Steel Crowns
3. Stainless Steel Tubes
4. Stainless Steel Wires

Reference Report No: MM0130-P004-R01, MM0130-P004-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

This EC certificate is valid till 2021-06-28.

Issue Date: 2013-07-03
Revision No.: 01 Recertification
Revision Date: 2018-06-29



Rukiye BALKAN
Deputy General Manager