

EC DECLARATION OF CONFORMITY

Device designation	EU Class	Annex IX Classification Rule
Orthodontic Metal Brackets, In-Ovation R In-Ovation L In-Ovation Mini Balance Ovation Generus Mini Ovation OmniArch MicroArch MTM No Trace Resolve	II a	5
Orthodontic Ceramic Brackets, In-Ovation C Ovation C In-Ovation Czir Allure Mystique Cryscera Resolve	IIa	5
Orthodontic Plastic Brackets, Elation	IIa	5
Lingual Attachments	IIa	5
Orthodontic Wires and accessories	II a	5
Orthodontic Bands	II a	5
Orthodontic Ligature	II a	5
Orthodontic Spring	II a	5
Orthodontic Retainers (includes Expansion Screws and Thermoplastics)	II a	5
Orthodontic Tubes, In-Ovation	II a	5
Orthodontic Elastomerics (30 or greater days in mouth)	II a	5
Orthodontic Adhesives / Cements*	II a	5
Dental Burs	II a	5
Polishing Disks	II a	5
X-Ray Film	II a	16
Interproximal Reduction Systems (IRS - Dental Hand pieces)	II a	5
Interproximal Reduction Systems - motor/contra-angle	II a	9
VistaDent Software	II a	16
Thermoforming plastic sheets	II a	5

* Orthodontic Cements and Orthodontic Adhesives Products have the same meaning.

DENTSPLY GAC International
One CA Plaza, Suite 100
Islandia, NY 11749, USA
1-800-645-5530

Route to Compliance	Annex II of MDD 93/42/EEC
Notified Body Address and ID#:	SGS United Kingdom Ltd. 202B Worle Parkway, Weston-super-Mare, BS22 6WA United Kingdom SGS 0120
CE Certificate Number:	US97/9988

The Manufacturer, DENTSPLY GAC International, hereby declares that the product(s) described above conform to the requirements of Council Directive 93/42/EEC and meet the relevant Essential Requirements of Annex I. All devices are designed, manufactured, and tested and released for sale in accordance with the technical documentation. DENTSPLY GAC International Division maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Part 820, EN ISO 13485:2012 and the European Union Council Directive 93/42/ EEC.

This declaration is made on the basis of the EC Certificate Full Quality Assurance Certificate # **US97/9988** issued by SGS United Kingdom Ltd., CE0120, in accordance with Annex II of the Directive, valid from 17 October 2014.

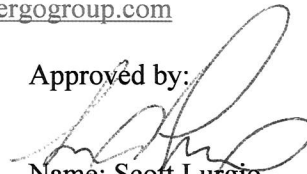
The device complies with EN ISO 13485:2012 under Certificate No. **US97/9987** issued by SGS United Kingdom Ltd., valid from 17 November 2015.

AUTHORIZED REPRESENTATIVE

Emergo Europe
Molenstraat 15
2513 BH
The Hague, The Netherlands
+ 31.70. 345.8570 – phone
+ 31.70.346.7299 – fax
Europe@emergogroup.com

Date: 07/27/2016

Approved by:



Name: Scott Lurgio

Title: QA/RA Director