DENTSPLY

ORTHO FRANCHISE

DENTSPLY GAC International
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EC DECLARATION OF CONFORMITY

Device designation	EU Class	Annex IX Classification Rule
Headgear, Facebows and other Headgear appliances	I	5
Dental Impression Materials	I	5
Polishing Strips	I	5
Relief Aid Products	I	5
Procedure Aid products	I	5
Cheek, Lip Retractors	I	5
Impression Dental Trays (Single Use / Reusable)	I	5
Floss	I	5
Mouth/Brace/Tongue Guards	I	5
Dental Hand Instruments	I	5
Dental Mirrors	I	5
Brushes (Applicators)	I	5
Saliva Ejector	I	5
Elastomerics (Separators)	I	5

Route to Compliance	Annex VII of MDD 93/42/EEC

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 under Certificate No. **US97/9987** issued by SGS United Kingdom Ltd., valid from 17 November 2015, and the European Union Council Directive 93/42/ EEC.

AUTHORIZED REPRESENTATIVE

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Date: 06/14/2016

Approved by:

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