

**GAC International LLC also trading as
Dentsply GAC, Dentsply GAC
International, Dentsply International
Inc., GAC International, GAC
International Inc., and GAC
TechnoCenter®**

One CA Plaza, Suite 100,
Islandia, NY, 11749, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)

For the following products

**Orthodontic brackets, wires, bands, elastomers, adhesive/cement products,
ligatures, springs, retainers, tubes, lingual attachments, dental burs, polishing
disks, x-ray film, interproximal reduction system, and orthodontic digital
imaging software.**

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 17 October 2014 until 24 September 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 September 2017
Issue 14. Certified since 30 May 1997

Certification is based on reports numbered WW/ME 07118

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com
SGS CE 01 0311
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Certificate US02/2815

The management system of

**GAC International LLC also trading
as Dentsply GAC, Dentsply GAC
International, Dentsply
International Inc., GAC
International, GAC International
Inc., and GAC TechnoCenter®**

One CA Plaza, Suite 100,
Islandia, NY, 11749, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

**Design and manufacture of orthodontic bands, brackets, wires,
elastomerics, adhesives, cements, Springs, Expanders, Lingual
Attachments, Retainers, Aligners, Interproximal Reduction System,
Dental Burs, Polishing Disks, X-ray Film and orthodontic digital
imaging software.**

Effective Date 28 November 2014 Expiry Date 28 November 2017

Re certification audit due before 24 September 2017

Valid subject to satisfactory surveillance audits.

Issue 10. Certified since 28 December 2003

Authorised by
Jan Saunders – Business Manager

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
CMDCAS recognised registrar

SGS 13485 CMDCAS 0311

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Certificate US97/9987

The management system of

GAC International LLC also trading as Dentsply GAC, Dentsply GAC International, Dentsply International Inc., GAC International, GAC International Inc., and GAC TechnoCenter®

One CA Plaza, Suite 100,
Islandia, NY, 11749, United States
has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design and manufacture of Orthodontic Bands, Brackets, Wires, Elastomers, Non-powered hand Instruments, Adhesives, Cements, Headgear, Face-bows, Orthodontic Accessories, Saliva Ejectors, Retractors, Bite Sticks, Springs, Expanders, Lingual Attachments, Brace Guards, Retainers, Aligners, Interproximal Reduction System, Dental Burs, Mirrors, Polishing Disks, X-ray Film and orthodontic digital imaging software.

This certificate is valid from 24 November 2014 until 24 September 2017 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 September 2017
Issue 17. Certified since 30 May 1997

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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