

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Dentsply LLC Professional Division,
also dba "Dentsply Professional",
also dba "Dentsply Pharmaceutical",
also dba "Dentsply Rinn", also dba
"Sultan Healthcare", also dba "Dentsply Sirona", also
dba "Dentsply Sirona Preventive
1301 Smile Way York
Pennsylvania
17404
USA

Facility ID Number: F000159

Holds Certificate No:

MDSAP 691246

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-03-24

Effective Date: 2024-09-12

Expiry Date: 2026-03-23



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 691246**

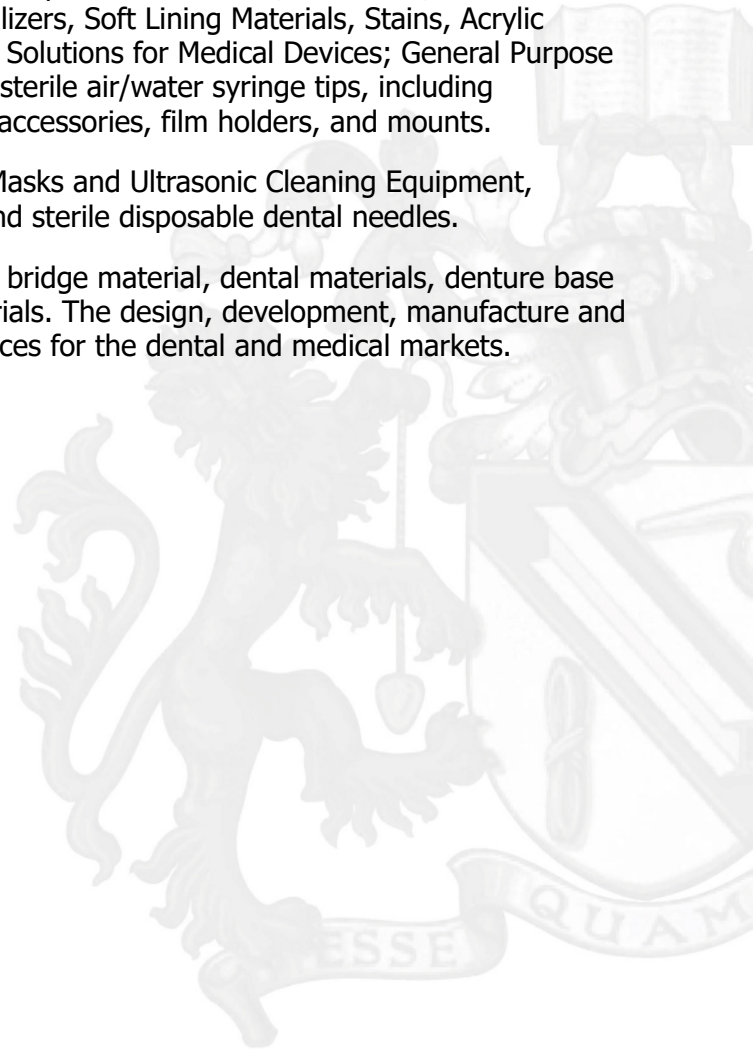
Registered Scope:

The design, development, manufacture, servicing, installation and distribution of ultrasonic scalers and inserts, endosonic inserts, nozzles, trainers, viewers, duplicators, and other chairside products for periodontal and endodontic use.

The design, development, manufacture and distribution of preventive and infection control products including abrasive polishing agents, infection control barriers, sealants, conditioners, and etchants for the dental industry, Dental Products (Dental Resins, Cements, Impression Materials, Adhesives, Porcelain Bonding Adhesive, Endodontic Filling Materials and Devitalizers, Soft Lining Materials, Stains, Acrylic Varnish); Liquid Chemical Cleaning/Disinfecting/Sterilizing Solutions for Medical Devices; General Purpose Cleaning Solutions and Pharmaceutical Preparations, non-sterile air/water syringe tips, including conversion kit (adaptor), prophy cups and brushes, x-ray accessories, film holders, and mounts.

The distribution of Sterilization Packaging Material, Face Masks and Ultrasonic Cleaning Equipment, Disposable Fluoride Trays, Disposable Impression Trays and sterile disposable dental needles.

The design and manufacture of artificial teeth, crown and bridge material, dental materials, denture base materials, dental equipment and machinable dental materials. The design, development, manufacture and servicing of digital radiographic imaging systems and devices for the dental and medical markets.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.