



Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Dental Manufacturing S.p.A.

Via Ca' Mignola Nuova, 1699

Badia Polesine (RO)

45021 Italy

Facility ID Number: F002742

Holds Certificate No: MDSAP 692398

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

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

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

Design, production and distribution of acrylic teeth, PMMA Discs and cubes, polymers for crowns, bridges and dentistry, and dental impression trays.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-12-04 Effective Date: 2024-12-04 Expiry Date: 2027-12-03

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MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."