

Certificate Number US201819944044

The quality management system of

SGS

Great Lakes Dental Technologies

200 Cooper Avenue, Tonawanda, NY, 14150, United States

Dun & Bradstreet D-U-N-S Identification number : 04-185-4332

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP(ISO 13485:2016)

Australia
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.8) – Full
Quality Assurance Procedure (including design)
Canada
Medical Devices Regulations – Part 1 SOR 99/262
USA
MHLW Ministerial Ordinance 169, Article 4 to Article 68 / PMD Act
United States
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

**Design, manufacture and distribution of thermal forming materials,
acrylic resins, operatory equipment, orthodontic wire/wire forms
and appliances and training services for the orthodontic
and restorative industry.**

This certificate is valid from
Effective Date: 2020-09-01 until Expiry Date: 2023-08-31
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2023-07-09
Issue 1. Certified since 2020-09-01

Authorised by J Hall
Business Manager

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