Certificate US20/819944044

The quality management system of

Great Lakes Dental Technologies

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

Facility number: F002994

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Canada: Medical Device Regulations SOR/98-282, Part 1
Japan: MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
Japan PMD Act (as applicable)
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

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 2023-08-31 until Expiry date 2026-08-31 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2020-09-01

Authorised by
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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.