

Certificate US20/819944044

The quality management system of

Great Lakes Dental Technologies, Ltd.

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 Devices Regulations (SOR/98-282) Part 1 - General

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 Management System Regulation

For the following activities

Design and development, 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 2026-08-31 until Expiry date 2029-08-31 and remains valid subject to satisfactory surveillance audits.

Issue 4. 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.



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