Certificate US20/819943831

The quality management system of

Lares Research

295 Lockheed Avenue, Chico, CA, 95973, United States Of America

Facility number: F003997

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.155 (2020) 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, distribution and service of dental handpieces, dental handpiece couplers, and electric motors and consoles for dental applications.

This certificate is valid from Effective date 2023-03-09 until Expiry date 2026-03-08 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2020-03-12

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Authorised by Geofrey De Visscher Head of Notified Body 1639

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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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