Certificate US21/819944815

The quality management system of

Reliance Orthodontic Products, Inc.

1540 West Thorndale Avenue, Itasca IL 60143, United States of America

Facility number: F006082

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
Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009 - Vigilance
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
The design, manufacture and distribution of Dental Orthodontic Adhesives, Band Cements, Sealants, Conditioners, Primers, Etchants, Prophy Angles, Points, Burs, Wires, Archwires, Hooks, Ortho FlexTech, Elastics, Orthodontic Hardware and Aligner instruments for the Dental Orthodontic profession.

This certificate is valid from Effective date 2023-04-19 until Expiry date 2026-04-18 and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 2020-04-23

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.