

Certificate US24/00000463

The quality management system of

Specialty Appliances, LLC

4905 Hammond Industrial Drive, Cumming, GA, 30041, United States Of America

Facility number: F007288

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Canada: Medical Device Regulations SOR/98-282, Part 1

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 distribute non-active orthodontic appliances and components.

This certificate is valid from Effective date 2024-11-13 until Expiry date 2027-11-13 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 2024-11-13

Certified activities performed by additional sites are listed on subsequent pages.



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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Certificate US24/00000463, continued
Specialty Appliances, LLC

SGS

MDSAP (ISO 13485:2016)

Issue 1

Sites

Campus:
4890 Hammond Industrial Drive, Cumming, GA, 30041, United States Of America



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