

**MDSAP**

Medical Device Single Audit Program



America

CERTIFICATE

No. QS6 083673 0002 Rev. 04**Certificate Holder:****Shaily Engineering Plastics Limited**

Survey No. 363,364 & 366, Rania

Taluka-Savli

Dist- Vadodara, Gujarat 391780

INDIA

Certification Mark:**Scope of Certificate:****Contract Design, Development and Manufacturing of Reusable and Disposable Pen Injectors, Rectal Applicators, Dry Powder Inhalers, Plastic Bottle Applicators with Brush, Underarm Applicators****Standard(s):****ISO 13485:2016****Regulatory Authority(ies):****Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 083673 0002 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:QS6_083673_0002_Rev_04)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:**F003942****Report No.:****201530002249****Effective Date:****2025-07-22****Expiry Date:****2028-07-21**

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(Renee Walker)
Director, US Certification Body, MHS



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No. QS6 083673 0002 Rev. 04

Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Shaily Engineering Plastics Limited

Survey No. 363,364 & 366, Rania, Taluka-Savli, Dist-Vadodara, Gujarat 391780, INDIA

Facility Scopes:

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