







Product Service

Certificate

No. Q8 083673 0003 Rev. 02

Holder of Certificate: Shaily Engineering Plastics Limited

Survey No. 363,364 & 366, Rania

Taluka-Savli

Dist- Vadodara, Gujarat 391780

INDIA

Certification Mark:



Scope of Certificate:

The provision of Design and Development, Manufacturing, Testing and Supplies of Injection moulded, printed, laser marked, ultrasonic welded, siliconized parts/components and sub assemblies / assemblies for Pen injectors, Auto Injectors, Respiratory Inhalers, Sprays, Pumps, and Drug Applicators.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q8 083673 0003 Rev. 02

 Report No.:
 201530002249

 Valid from:
 2025-08-27

 Valid until:
 2028-08-26

Date, 2025-08-20

C. UIL

Christoph Dicks Head of Certification/Notified Body







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Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Shaily Engineering Plastics Limited

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

Gujarat 391780, INDIA

See Scope of Certificate

Shaily Innovations Ltd

6th Floor, Amp House, Dingwall Road, Croydon, CR0 2LX,

UNITED KINGDOM

Administrative Activities

Shaily Innovations Limited

5, Pegasus House, Olympus Ave, Royal Leamington Spa,

Warwick, CV34 6LW, UNITED KINGDOM

The provision of Design and Devlopment of Injection moulded, printed, laser marked, ultrasonic welded, siliconized and sterilized parts/components and subassemblies / assemblies for pen injectors, Auto injectors, Respiratory Inhalers, Sprays, Pumps and Drug Applicators.

Shaily Innovations Limited

Suite B, Floor 2, Profile West, 950, Great West Road, Brentford, TW8 9ES, UNITED KINGDOM

The provision of Design and Devlopment of Injection moulded, printed, laser marked, ultrasonic welded, siliconized and sterilized parts/components and subassemblies / assemblies for pen injectors, Auto injectors, Respiratory Inhalers, Sprays, Pumps and Drug Applicators.

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