





Product Service

Certificate

No. Q8 083673 0003 Rev. 01

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. 01

Report No.: 201530000216_CN

 Valid from:
 2024-10-21

 Valid until:
 2025-08-26

Date, 2024-10-21

Christoph Dicks

Head of Certification/Notified Body





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ISO 13485:2016 Applied Standard(s):

(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 (UK) Limited

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

UNITED KINGDOM

The provision of Design and Development 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.

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