

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE

This certifies that the quality system of

Rodon Limited Partnership

2800 Sterling Dr., Hatfield, PA 19440, USA

is registered by Systems Certification Body in recognition of a Quality Management System which fulfills the requirement of

ISO 13485:2016

Scope of Registration

Injection molding of non-sterile components for use in general, non-active and non-implantable medical devices.

Certificate No: 1117367

Certificate Decision/Re-Issue Date: 07/26/2023 Certificate Issue Date: 07/26/2023 Certificate Expiry: 07/25/2026

Site Structure: Single Site w/ Additional Address

SHIPLEY DEWI, SR. VICE PRESIDENT OF

MANAGEMENT SYSTEM REGISTRATION SERVICES

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Appendix to Certificate No: 1117367

Includes Facilities Located At (Single Site w/ Additional Address):

Central Function: Rodon Limited Partnership

2800 Sterling Dr., Hatfield, PA 19440, USA

Scope of Registration: Injection molding of non-sterile components for use in general, non-active and non-implantable medical devices.

Site #1: Rodon Limited Partnership

2990 Bergey Road, Hatfield, PA 19440, USA

Scope of Registration: Warehousing and distribution of non-sterile injection molded plastic components for use in medical devices.

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Site Structure: Single Site w/ Additional Address