Certificate of Registration

Certificate number

28118.260724

File number

A29043 / BR5540

Initial issue date

2023-07-24

Cycle start date

2026-07-24

Effective date

2026-07-24

Expiry date

2029-07-23

CERTIFIED MANAGEMENT SYSTEM

MDSAP Medical Device Single Audit Program

Exelint International, Co.

2500 Santa Fe Ave
Redondo Beach, California 90278 UNITED STATES

Facility ID: F006495

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016
EN ISO 13485:2016/A11:2021

with additional regulatory requirements listed on the final page of this certificate.

Design and Development, Manufacturing and Distribution of sterile non-active non-implantable medical devices including Hypodermic Needles, Disposable Syringes, Disposable Syringes with Needles, Insulin Syringes, Insulin Pen Needles, Safety Hypodermic Needles, Scalp Vein Sets, Blood Collection Sets, Safety Scalp Vein Sets, Huber Needles, Huber Infusion Sets, Safety Huber Infusion Sets, IV Administration Sets, IV Extension Sets, Dental Needles, Multi-Sample Blood Collection Needles, Luer Adapters, Multi-Sample Luer Holder with Pre-Attached Luer Adapter, Injection Plugs, Surgical Blades, Disposable Scalpels, Spinal Needles, IV Catheters, Syringes with Safety Needles, Pressure Bandages, IV Cannulas, Dermal Curettes."

Certificate with Addendum(s) totals 3 pages.

Authorized by:

Paul Daysh
Operations manager – Medical Regulatory

Check certificate status: here

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC, UL Solutions medical regulatory services is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

UL Solutions

Addendum 1

Site	Company Name	Location	Performing
1-1	Exelint International, Co.	2500 Santa Fe Ave Redondo Beach California 90278 UNITED STATES Facility ID: **F006495**	Distribution/logistics, QA, RA and management

Additional Regulatory Requirements

Exelint International, Co.
2500 Santa Fe Ave
Redondo Beach, California 90278 UNITED STATES

Facility ID: F006495

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
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:
- Medical Devices Regulations – Part 1- SOR 98/282

Japan:
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)