Certificate US23/00000077

The quality management system of

Kova International, Inc.

7272 Chapman Avenue, Suite B, Garden Grove, CA 92841 United States Of America

Facility number: F006387

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: 1 - Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Canada: 1 - Medical Device Regulations SOR/98-282, Part 1
USA: 1 - 21 CFR Part 803 - Medical Device Reporting, 2 - 21 CFR Part 806 - Reports of Corrections and Removals, 3 - 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 4 - 21 CFR Part 820 - Quality System Regulation

For the following activities
Design and Manufacture of in-vitro diagnostic reagents (Urine Controls) used in the diagnosis and management of disease status

This certificate is valid from Effective date 2023-02-14 until Expiry date 2026-02-02 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 2023-02-14

Authorised by
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Head of Notified Body 1639

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.