By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

PT ONEJECT INDONESIA
Jl. Anggrek VII, No.41,
Kawasan Industri Terpadu Indonesia China (KITIC),
Kab. Bekasi,
Jawa Barat
17337
Indonesia

Facility ID Number: F007507

Holds Certificate No: **MDSAP 810149**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and manufacture of sterile auto-disable syringes, disposable syringes with hypodermic needle and safety needle, sterile and non-sterile single-use venous blood specimen containers.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-10-07 Effective Date: 2024-10-07 Expiry Date: 2027-10-06

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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