



Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN 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

Holds Certificate Number: MD 760987

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

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. The provision of contract electron beam sterilization service fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-05-25 Effective Date: 2024-10-08 Latest Revision Date: 2024-10-08 Expiry Date: 2027-10-06

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...making excellence a habit."





This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract, An electronic certificate can be authenticated online.

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