

Certificate of Registration

QUALITY 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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