

# Certificate

**Management System as per  
ISO 13485 : 2016**



The Certification Body TÜV NORD Indonesia hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

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

operates a management system in accordance with the requirements of ISO 13485:2016 and will be assessed for conformity within the 3 year term of validity of the certificate

**Design and Manufacture of Sterile Auto-Disable Syringes and Disposable Syringes with Hypodermic Needle and Safety Needle, Sterile and Non-Sterile of Single-Use Venous Blood Specimen Containers, In-Vitro Diagnostic Instruments – Rapid, Automated and Semi-Automated Hematology Devices, and Clinical Laboratory Instruments; and Provision of E-Beam Sterilization Services in accordance with ISO 11137-1:2006**

Certificate Registration No. **01 05 H 24000595**  
Audit Report **OD.AA.RC.2406047**

Valid from **2024-08-28**  
Valid until **2027-07-15**  
Initial Certification **2021-07-16**



Jakarta, 2024-08-28

Certification Body at TÜV NORD Indonesia

