



**KEMENTERIAN KESEHATAN - REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
DIREKTORAT PENGAWASAN ALAT KESEHATAN DAN PKRT**

*MINISTRY OF HEALTH - REPUBLIC OF INDONESIA
DIRECTORATE GENERAL OF PHARMACEUTICAL AND MEDICAL DEVICES
DIRECTORATE OF POST MARKET CONTROL OF MEDICAL DEVICES AND HOUSEHOLD PRODUCT*

**SERTIFIKAT
A CERTIFICATE**

**CARA PEMBUATAN ALAT KESEHATAN YANG BAIK
GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES**

NOMOR FK.01.04/1/025/2017
NUMBER FK.01.04/1/025/2017

Diberikan kepada

Presented to

PT. ONEJECT INDONESIA

Jl. Olympic Raya Kav. B-9, Kawasan Industri Sentul Kec. Babakan Madang
Kab. Bogor - Jawa Barat Telp. 021-87917422, Fax. 021-87902761

**Telah memenuhi syarat untuk mendapatkan
Sertifikat Cara Pembuatan Alat Kesehatan yang Baik**

Has been approved to get Certificate of Good Manufacturing Practice for Medical Devices

Ruang lingkup

Scope

Produksi Peralatan Rumah Sakit Umum dan Perorangan: Autodisable Syringe
with/without Needle; Hypodermic Syringe Needle with Re-use Prevention Feature;
Disposable Syringe with/without Needle; IV infusion Set; Hypodermic Needle,
Peralatan Obstetrik Ginekologi: Intrauterine Device



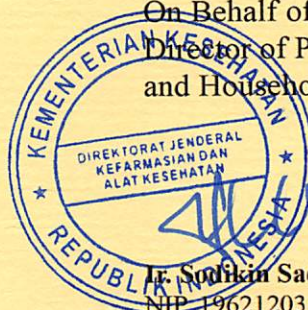
Tanggal Persetujuan
Approval Date

27 NOV 2017

Berlaku hingga
Valid thru

27 NOV 2022

A.n Direktur Jenderal
Direktur Pengawasan Alat Kesehatan dan PKRT
On Behalf of Director General
Director of Post Market Control of Medical Devices
and Household Product



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