



## E008: Injection devices for immunization



<b>Product name:</b>	Oneject 0.3ml AD
<b>IMD-PQS Code:</b>	E008-086
<b>Status:</b>	Prequalified
<b>Date of acceptance:</b>	31 Aug 2021
<b>Appliance type:</b>	E008
<b>Product description:</b>	Oneject 0.3ml AD
<b>Manufacturer:</b>	PT Oneject Indonesia
<b>Manufacturers Reference:</b>	Oneject 0.3ml AD
<b>Country of Manufacture:</b>	Indonesia
<b>Address:</b>	Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor Jawa Barat Indonesia
<b>Telephone:</b>	+62 21 879 17 422
<b>Email:</b>	<a href="mailto:niken.permatasari@oneject.co.id">niken.permatasari@oneject.co.id</a>
<b>Website address:</b>	<a href="http://www.oneject.co.id">www.oneject.co.id</a>
<b>Valid until:</b>	31 May 2026

### Specifications

#### PRODUCT SPECIFICATIONS - MAIN

<b>Vaccine capacity (mL)</b>	0.30	<b>Markings</b>	CE mark
<b>Syringe material(s)</b>	Polypropylene	<b>RUP mechanism</b>	Locked / broken plunger
<b>Packaging &amp; Sterility Assurance</b>	Yes	<b>Other needle size options</b>	Yes
<b>AD Number pieces</b>	3 pieces	<b>Auto-disabling at:</b>	End of injection
<b>Needle Size</b>	24Gx1" (0.55 x 25 mm)	<b>AD Sub Category</b>	Simple AD
<b>AD Primary packaging</b>	Blister pack		

<b>Comments</b>	Graduation 0.3mL. Average deadspace 0.021mL
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#### PRICE AND SHIPPING

<b>Shipping volume (m3)</b>	0.057	<b>Weight per package (Kg)</b>	7.8000
<b>Pieces per package</b>	1600	<b>Minimum order (unit)</b>	16000.00
<b>Price 1</b>	Upon request to manufacturer	<b>Year of base price</b>	2021
<b>Incoterms</b>	FOB		

#### QUALITY STANDARD

<b>Quality Standard</b>	ISO 13485	<b>Specification Reference</b>	Applicable PQS specification: ISO 7886/3 Applicable PQS VP(s):
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#### PRODUCT SITES

<b>Organization name</b>	PT Oneject Indonesia
<b>Address</b>	Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor Jawa Barat Indonesia

<b>Current PQS status:</b>	<i>Prequalified</i>	<b>Valid until:</b>	<i>31 May 2026</i>
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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.