



## E008: Injection devices for immunization



|                                 |                                                                                                                       |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| <b>Product name:</b>            | ONEJECT AD Syringe 0.5ml (K1)                                                                                         |
| <b>IMD-PQS Code:</b>            | E008-131                                                                                                              |
| <b>Status:</b>                  | Prequalified                                                                                                          |
| <b>Date of acceptance:</b>      | 22 Sep 2026                                                                                                           |
| <b>Appliance type:</b>          | E008                                                                                                                  |
| <b>Product description:</b>     | AD syringe 0.5ml                                                                                                      |
| <b>Manufacturer:</b>            | PT Oneject Indonesia                                                                                                  |
| <b>Manufacturers Reference:</b> | ONEJECT AD Syringe 0.5ml (K1)                                                                                         |
| <b>Country of Manufacture:</b>  | Indonesia                                                                                                             |
| <b>Address:</b>                 | JL. Anggrek VII No.41, Kawasan Industri Terpadu<br>Indonesia China (KITIC),<br>Kab. Bekasi<br>Jawa Barat<br>Indonesia |
| <b>Telephone:</b>               | +62 21 879 17 422                                                                                                     |
| <b>Email:</b>                   | <a href="mailto:pqs.registration@oneject.co.id">pqs.registration@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 2027                                                                                                           |

## Specifications

### PRODUCT SPECIFICATIONS - MAIN

|                                            |                         |                                  |                              |
|--------------------------------------------|-------------------------|----------------------------------|------------------------------|
| <b>Vaccine capacity (mL)</b>               | 0.50                    | <b>Graduations (ml)</b>          | 0.50                         |
| <b>Markings</b>                            | CE Mark                 | <b>Syringe material(s)</b>       | Polypropylene                |
| <b>Packaging &amp; Sterility Assurance</b> | Yes                     | <b>Other needle size options</b> | Yes                          |
| <b>Units per package</b>                   | 1600.00                 | <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 location</b>               | Upon completion of injection |
| <b>AD Mechanism</b>                        | Locked / Broken Plunger | <b>AD Primary packaging</b>      | Blister pack                 |

### PRICE AND SHIPPING

|                             |                              |                                |          |
|-----------------------------|------------------------------|--------------------------------|----------|
| <b>Shipping volume (m3)</b> | 0.06                         | <b>Weight per package (Kg)</b> | 7.7000   |
| <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>      | 2005     |
| <b>Incoterms</b>            | FOB                          |                                |          |

### QUALITY STANDARD

|                         |           |                                |                                                                                 |
|-------------------------|-----------|--------------------------------|---------------------------------------------------------------------------------|
| <b>Quality Standard</b> | ISO 13485 | <b>Specification Reference</b> | Applicable PQS specification:<br>ISO 7886-3 Applicable PQS<br>VP(s): ISO 7886-3 |
|-------------------------|-----------|--------------------------------|---------------------------------------------------------------------------------|

### PRODUCT SITES

|                          |                                                                                                                    |
|--------------------------|--------------------------------------------------------------------------------------------------------------------|
| <b>Organization name</b> | PT Oneject Indonesia                                                                                               |
| <b>Address</b>           | Jl. Anggrek VII No.41, Kawasan Industri Terpadu Indonesia China (KITIC),<br>Kab. Bekasi<br>Jawa Barat<br>Indonesia |

|                            |                     |                     |                    |
|----------------------------|---------------------|---------------------|--------------------|
| <b>Current PQS status:</b> | <i>Prequalified</i> | <b>Valid until:</b> | <i>31 May 2027</i> |
|----------------------------|---------------------|---------------------|--------------------|

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.