

**E008: Auto-disable syringe for fixed dose immunization**

PQS code: E008/071
Description: Single Use auto-disable needle-free jet injector
Manufacturer's reference: PharmaJet® Tropis®
Manufactured in: United States
Company: PharmaJet, Inc.
Address: 400 Corporate Circle,
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Golden, Colorado 80401
USA
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Email: Chris.Cappello@pharmajet.com
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Specifications

Reset station	Injector	Needle free syringe	Filling adapter
Reference manufacturer C501-20	Reference manufacturer: C501-10	Reference manufacturer: C501-34	Reference manufacturer: C501-43 & C501-46
Activation: manual	Administration: IM or SC	Nominal capacity and graduation: 0.5ml	Material of adaptor: Polycarbonate
Force applied:	Energy source: spring	Main materials of syringe: Polycarbonate	Compatibility only with the Stratis needle-free syringe
Life time cycles: 20,000 min	Main material: ABS, stainless steel	Prevented from reuse by: Plunger break before injection	Intended for one vial use for field-filling of syringes
Carrying case IP: 55	Inadvertent actuation prevention feature	Primary packaging: paper blister packs	Primary packaging: paper blister packs
Warranty 2 years	Warranty 2 years	Number of syringes per box: 100 units	Number of adapters per box: 75 units
The PharmaJet Stratis™ needle-free injection system is intended to deliver various medications and vaccines either intramuscularly or subcutaneously by means of narrow precise fluid stream, which penetrates body tissues.			
Quality system Standard	-----, ISO 13485,	Product standard:	ISO 7886-3; -----

Comments: Single-use auto-disable needle-free jet injector
Note: Jet Injectors (single-use auto-disable needle-free syringe injectors) as medical devices (Class II) are regulated by National Regulatory Authorities. A Jet injector prequalified by the WHO PQS programme to deliver medications and vaccines is to be used according to label to deliver ONLY those medications and vaccines that have been approved by the relevant Authorities.

Current PQS status: *pre-qualified ; 04 Jun 2018*

Valid until : *May 2023*

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased