



E008: Injection devices for immunization



Product name:	Pharmajet Stratis®
IMD-PQS Code:	E008-050
Status:	Prequalified
Date of acceptance:	31 Jan 2013
Appliance type:	E008
Product description:	single-use auto-disable needle-free jet injector
Manufacturer:	PharmaJet, Inc.
Manufacturers Reference:	Pharmajet Stratis®
Country of Manufacture:	United States of America
Address:	400 Corporate Circle, Suite N Golden, Colorado 80401 USA United States of America
Telephone:	+1 303 526-4278
Email:	brent.carpenter@pharmajet.com
Website address:	http://www.pharmajet.com/
Valid until:	31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Vaccine capacity (mL)	0.50	Graduations (ml)	0.50
Markings	FDA 510(k); CE 556625	RUP mechanism	Plunger break
Packaging & Sterility Assurance	Yes	Other needle size options	No
AD Number pieces	2 pieces	Auto-disabling at:	Start of injection
AD Sub Category	Jet injector	AD Primary packaging	Blister pack

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. Reset station Injector: Reference manufacturer C501-20 Needle free syringe: Reference manufacturer C501-32 & C501-34 Filling adapter: Reference manufacturer C501-43 & C501-46 Injector: Reference manufacturer C501-10 Minimum order (units): 1 set Units per package: Syringes, 250/box; adaptors, 75/box
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PRICE AND SHIPPING

Shipping volume (m3)	0.037	Weight per package (Kg)	3.2300
Pieces per package	1	Price 1	Upon request to mfr
Year of base price	2012	Incoterms	EXW

QUALITY STANDARD

Quality Standard	ISO 13485	Specification Reference	Applicable PQS specification: E008/JI01.1 Applicable PQS VP(s): E008/JI01-VP.1
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PRODUCT SITES

Organization name	PharmaJet, Inc.
Address	400 Corporate Circle, Suite N Golden, Colorado 80401 USA United States of America

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.