

E008:	Auto-disable syringe for fixed dose immunization
PQS code:	E008/050
Description:	single-use auto-disable needle-free jet injector
Manufacturer's reference:	Pharmajet Stratis®
Manufactured in:	United States
Company:	PharmaJet, Inc.
Address:	400 Corporate Circle, Suite N Golden, Colorado 80401 USA
Telephone:	+1 303 526-4278
Email:	Chris.Cappello@pharmajet.com
Web address:	http://www.pharmajet.com/

Specifications

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Reset station	Injector	Neelde 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 Pharma let StratisTM ner	edle-free injection system is inter	ded to deliver various medication	s and vaccines either		

The PharmaJet StratisTM 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; FDA 510(k); CE 556625		
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 ; 31 Jan 2013	Valid until	: May 2024		

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased