

WHO Immunisation Devices - Performance, Quality & Safety

E008: Injection devices for immunization

Product name: PharmaJet® Tropis®

IMD-PQS Code:E008-071Status:PrequalifiedDate of acceptance:06 Apr 2018

Appliance type: E008

Product description: Single Use auto-disable needle-free jet injector

Manufacturer:PharmaJet, Inc.Manufacturers Reference:PharmaJet® Tropis®Country of Manufacture:United States of America

Address: 400 Corporate Circle, Suite N Golden, Colorado 80401

United States of America

USA

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) 0.10 Markings -----

Packaging & Sterility Yes Auto-disabling at: End of injection Assurance

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.

PRICE AND SHIPPING

Price 1 Contact manufacturer Year of base price 2018

QUALITY STANDARD

Quality StandardISO 13485Specification ReferenceApplicable PQS specification:

E008/JI01.1 Applicable PQS VP(s): E008/JI01-VP.1

PRODUCT SITES

Organization name PharmaJet, Inc.

Address 400 Corporate Circle, Suite N Golden, Colorado 80401 USA

United States of America

Current PQS status: Prequalified Valid until: 31 May 2026

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.