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PQS Type-examination protocol

TITLE: Single-use auto-disable needle-free syringe injectors

Product verification protocol:	**E08/JI01-VP.1**
Applies to specification ref(s):	E08/JI01.1
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Contents:

1. Scope

This verification protocol describes supplementary testing and reporting requirements beyond those that are set out in ISO 21649 Needle-free injectors for medical use – Requirements and test methods for needle free jet injectors that use a sterile, single-dose, auto-disabling, needle-free syringe* intended for human clinical and medical use to deliver intra-dermal (ID), and/or subcutaneous (SC), and/or intra-muscular (IM) injections. Single-use and auto-disabling refer to the needle-free syringe or cartridge not the injector itself.

2. Normative references

The following referenced documents are indispensible for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

- EN ISO 13485:2003 *Medical devices – Quality management systems – Requirements for regulatory purposes*.
- IEC 60601-1 *Medical Electrical Equipment – General requirements for basic safety and essential performance.*
- ISO 21649 *Needle-free injectors for medical use – Requirements and test*

methods.

- ISO 7886-3 *Sterile hypodermic syringes for single use – Part 3: Auto-disable syringes for fixed dose immunization*.
- EN 62366 *Medical devices – Application of usability engineering to medical devices*.
- ISO 20282-1 *Ease of operation of everyday products – Part 1: Design requirements for context of use and user characteristics*.
- ISO/PAS 20282-3 *Ease of operation of everyday products – Part 3: Test method for consumer products*.
- Montreal Protocol: *The 1987 Montreal Protocol on Substances that Deplete the Ozone Layer* (as agreed in 1987).
- EU Directive 2002/96/EC on *Waste Electrical and Electronic Equipment*
- ISO/IEC 17025

3. Terms and definitions

Auto-disable or Auto-disabling: A feature or characteristic of the syringe or device that passively and automatically activates upon administration of the intended dose to prevent subsequent re-use of the syringe. No secondary or additional action on the part of the user shall be required (in order to avoid inadvertent or intentional re-use in the event such action is not taken). (adapted from ISO 7886-3).

Certification body: A government department or agency or third party organization that provides services for conformity assessment following completion of an independent assessment verification and qualification process.

Certified copies: Wherever a certified copy or certified photocopy is requested, the copy must be certified as a true copy of the original document by a person registered to practice law in the legal Manufacturer's country of origin and must be endorsed with the legal practitioner's official stamp and signature. Self-certification is not acceptable.

In writing: means communication by letter, fax or email.

Injector or Injection System: The mechanism or system into which the disposable syringe attaches. It is held by the user and provides the energy to effect the injection, along with other ergonomic, triggering, and safety components. Although normally re-usable for multiple injections, it may itself be disposable after single use.

Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Quality system: A quality system that has been certified by the appropriate regulatory or notified body as specified by table 2 of the PQS specification. This quality system must be in current and continuous compliance.

Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.

4. Applicability

Additional tests, beyond those required by ISO 21649 *Needle-free injectors for medical use – Requirements and test methods*, will be carried out in accordance with the quality system of the manufacturer and reviewed, verified and certified by the notified body as part of the manufacturers ISO 13485 certification procedure.

Type-examination will be carried out by an independent ISO/IEC 17025 testing laboratory, accredited by WHO.

5. Sample-examination checklist

5.1 *Evidence of conformity assessment*

Products must carry the CE mark and/or equivalent internationally accepted evidence of conformity assessment.

5.2 *Samples and supporting material*

The Legal Manufacturer or Reseller must supply the testing laboratory with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification clause 7. Two (2) samples of the product are required.

5.3 *Type-examination procedure*

- **Step 1:** (To be performed at WHO) Check all samples for similarities between different models[1], dissimilarities between samples of one model, and any defects or damage.
- **Step 2:** Record any differences between the samples ordered and those received.
- **Step 3:** Tabulate the following information for each model submitted for examination. Obtain any additional supporting information required in writing from the Legal Manufacturer or Reseller and attach this information to the report:

  Identification:
  - Code (a unique identifier to be assigned by the testing laboratory);
  - Model;
  - Legal Manufacturer or Reseller;
  - Country of origin;
  - Conformity assessment markings (e.g. CE mark).

  Performance characteristics:
  - Confirm that the device meets all applicable requirements of ISO 21649 *Needle-free injectors for medical use – Requirements and test methods*, and that all applicable tests have been carried out satisfactorily and have been fully documented.

[1] The purpose of this inspection is to establish whether products offered by competing companies are re-badged versions of an otherwise identical device.

Materials and construction:
- Materials of all major visible components;
- Materials used conform/do not conform to specification section 4.7;
- Weight: Maximum 1 kg (including syringe filled to usual dose volume), except that systems designed for mass campaigns using rapid, filling, loading, injecting, and unloading mechanisms may weigh up to 1.5 kg.

Warranty
- Warranty conforms/does not conform to specification clause 4.8;

Instructions:
- Instructions conform/do not conform to specification clause 4.11.

- **Step 4:** *Auto-disable feature*
  - Devices must meet the test requirements as set out in section 14.3 Auto disable feature of ISO 7886-3. Sterile hypodermic syringes for single use Auto disable syringes for fixed dose immunization.
  - Detail and tabulate the results.
- **Step 5:** *Cross contamination type examination.*
  - Inspect the auto-disable syringe/cartridge (the only part of the device intended for patient contact) according to the instructions for use and ensure these parts are auto-disable.
  - Detail and tabulate the results.
- **Step 6:** *Cycle time type examination*
  - The manufacturer must submit a copy of all testing procedures pertaining to claimed cycle time testing.
  - Determine whether the test procedure is reasonable and meets the respective requirement.
  - Detail and tabulate the results of this determination.
- **Step 7:** *Number of lifetime cycles*
  - The manufacturer must submit a copy of test evidence to support the number of lifetime cycles claimed.
  - Detail and tabulate the results of this determination.
- **Step 8:** *Ambient temperature range during transport and storage*
  - Detail the temperature range according to the manufacturer's specifications and tabulate the results of this determination.
- **Step 9:** *Water and dust resistance*
  - Confirm the instructions for use indicate that the injector is resistant to short duration exposure to water.
  - Review the manufacturer's specifications and IP55 rating test results to confirm that the carrying bag/case meets the IP55 rating as per IEC 60529
  - Detail the results of this determination.
- **Step 10:** *Ambient humidity range during transport, storage and use*
  - Review the manufacturer's specifications and test results to confirm that the device will operate in a humidity range of 5% to 95% RH, non-condensing.
  - Detail the results of this determination.
- **Step 11:** *Power source type examination*
  - Detail the power source of the device and confirm that it is manually, gas or electrically powered.

- **Step 12:** *Injector hand piece weight*
  - Weigh the device. Confirm that it meets the requirement.
  - Detail and tabulate the results of this determination.
- **Step 13:** *Disposable syringe filling*
  - Using the instructions for use (and if necessary, any provided vial adapter) fill a syringe from both a vial and an ampoule.
  - Record whether the syringe was successfully filled using the provided instructions and accessories.
- **Step 14:** *Human factors – general*
  - Review the device specifications and test results to confirm that the device has been tested in accordance with ISO 20282-3 and is in compliance with ISO 20282-1.
  - Detail the results of this determination.
- **Step 15:** *Skill level*
  - The manufacturer must submit a copy of all training materials and test evidence to show that training of the device does not exceed 1 hr and 20 injections.
  - Detail the results of this determination.
- **Step 16:** *Handedness*
  - Inspect the device to ensure that it is equally usable by both left and right handers.
  - Detail the results of this determination.
- **Step 17:** *Arming/delivering forces*
  - The manufacturer must submit a copy of all testing procedures pertaining to Arming/Delivery forces.
  - Determine whether the test procedure is reasonable and complies with the requirements of ISO 20282-1 and 20282-3.
  - Detail and tabulate the results of this determination.
- **Step 18:** *Repetitive use*
  - Review the device specifications to confirm that the device has been tested according to ISO 20282-3 and is in compliance with ISO 20282-1.
  - Detail the results of this determination.
- **Step 19:** *Pinch points*
  - Inspect the device to confirm that use of the device does not result in pinching of the operator's skin.
  - Detail the results of this determination.
- **Step 20:** Take a three quarter view digital photograph of each sample.
- **Acceptance criteria:** Inspection indicates full conformity with all major specification requirements.

5.4 Criteria for qualification

A final report must be issued after the type-examination is complete. The report must contain the following data and analyses:

- **Summary:** Conclusions and recommendations.
- **Type-examination:** Comments on samples received, tabulated data and photographs of samples.

- **Step 4: Auto-disable features:** Detailed testing procedure and results. Reference and include testing procedure in annex.
- **Step 5: Cross contamination:** Detailed inspection procedure and results. Reference and include inspection procedure in annex.
- **Step 6: Cycle time:** Detailed testing procedure and results. Reference and include testing procedure in annex.
- **Step 7: Number of lifetime cycles:** Test evidence and results
- **Step 8: Ambient temperature range during transport and storage:** Statement of temperature range
- **Step 9: Water and dust resistance:** Statement of IP rating and resistance of device to water.
- **Step 10: Ambient humidity range during transport, storage and use**
- **Step 11: Power source:** Statement of power source
- **Step 12: Injector hand piece weight:** Statement of hand piece weight
- **Step 13: Disposable syringe filling:** Description of syringe filling method.
- **Step 14: Human factors – general:** Statement of compliance with ISO 20282-1 and ISO 20282-3.
- **Step 15: Skill level:** Test evidence and results
- **Step 16: Handedness:** Statement that device is equally usable by both right and left handers.
- **Step 17: Arming/delivering forces:** Detailed testing procedure and results. Reference and include testing procedure in annex.
- **Step 18: Repetitive use:** Statement of compliance with ISO 20282-1 and ISO 20282-3.
- **Step 19: Pinch points:** Statement of compliance with ISO 20282-1 and ISO 20282-3.
- **Annexes:** Additional supporting documentation requested and received from the Legal Manufacturer or Reseller during the course of the type-examination.

6. Quality control checklist

6.1 *Quality control standard*

All testing and reporting must be carried out in accordance with the manufacturer's quality system. If the manufacturer is ISO 13485 certified, a copy of the current certificate must be included. If the device is FDA approved/cleared, the manufacturer's FDA registration number and date of last inspection must be included.

6.2 *Quality control checklist*

An on-site inspection of the manufacturing plant is not required.

7. Pre-qualification evaluation

A product will qualify for inclusion on the register of PQS pre-qualified single-use auto-disable needle-free syringe injectors, in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification E08/JI01.1.

8. Modified products

The legal manufacturer or reseller must notify WHO in writing of any changes which affect the performance of the product. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the product, WHO may request full or partial re-verification based on the type-examination procedures described in this document.

Revision history			
Date	Change summary	Reason for change	Approved
13.04.2010	Revised to include comments and changes by Andrew Garnett (Gene Saxon)	Drafting process	
21.04.2010	Revised to include reference numbers and incorporate comments from FORCE Technology	Drafting process	