Standard format for a type-examination protocol

WHO/XXX
IMD-PQS Type-examination protocol Original:
English

Distribution: General

TITLE: <Description>

Product verification protocol:	<IMD-PQS category>/<unique reference>
Applies to specification ref(s):	<IMD-PQS category>/<unique reference>
Issue date:	<Date>
Date of last revision:	<Date>

Contents: <list the content down to level 1.1.1>

1. Scope: <briefly describe the purpose of the type examination protocol>

2. Normative references: < list ISO/IEC and other standards that apply to the protocol and list any other relevant WHO product verification protocols>

3. Terms and definitions: <define any specific terms used in the protocol, particularly terms which may not be widely understood>

4. Applicability: <state who will carry out the sample examination and state who will carry out on-site inspection of the manufacturer's production facilities (where relevant)>

5. Sample-examination checklist:

5.1 Type examination certificates: < list acceptable type-examination certifiers and state the form in which evidence of type-examination is to be provided >

5.2 Number of samples: <state minimum number of samples to be evaluated>

5.3 Sample checklist: <list product features that are to be examined and describe how each item in the list is to be evaluated, including ergonomic, health and safety and 'universal design' features>

5.4 Criteria for qualification: <state the minimum requirements for prequalification>

6. Quality control checklist:

6.1 Quality control standards: < list acceptable quality control standards (e.g. ISO 9001) and state the form in which evidence of conformity is to be provided>

6.2 Quality control checklist: <list the production quality control features that are to be examined in the course of the on-site inspection (if applicable)>

6.3 Criteria for qualification: <state the minimum requirements for prequalification>

7. **Prequalification evaluation:** <state the overall minimum requirements for prequalification taking account of results from Clauses 5.4 and 6.3 and including any weighting system that may be needed >
8. **Modified products:** <describe the procedure for re-checking products that are already prequalified, but which have subsequently been modified by the manufacturer. This procedure may not involve full re-verification.>

Annexes: < as required>

Revision history

Date	Change summary	Reason for change	Approved
dd mm yy	< change item> < etc.>	< reason for change> < etc.>	<name>