Standard format for a type-examination protocol

WHO/XXX
IMD-PQS Type-examination protocol
English

Original:
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**

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