Standard format for a type-testing protocol

**WHO/XXX**
**IMD-PQS Independent type-testing protocol**

**TITLE:** <Description>

**Product verification protocol:** <IMD-PQS category>/<unique reference>

**Applies to specification ref(s):** <IMD-PQS category>/<unique reference>

**Date of origin:** <Date>

**Date of last revision:** <Date>

**Contents:** <list the content down to level 1.1.1>

1. **Scope:** <briefly describe the purpose of the independent type-testing protocol>

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

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 type-testing and state who will carry out on-site inspection of the manufacturer’s production facilities (where relevant)>

5. **Type-testing procedure**
   5.1 **Evidence of conformity assessment:** <state the required evidence of conformity assessment>
   
   **Number of samples:** <state minimum number of samples to be evaluated>
   
   5.2 **Test procedure:** <set out the technical details of the test procedure, including testing ergonomic, health and safety and ‘universal design’ features>
   
   5.3 **Test criteria for qualification:** <state the minimum requirements for qualification>

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 **Quality control evaluation:** <state how the quality control checklists are to be evaluated>

7. **Prequalification evaluation:** <state the minimum criteria for prequalification taking account of results from Clauses 5.3 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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