World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT
	VACCINES ASSESSMENT TEAM

TEMPLATE		
STANDARD FORMAT FOR A TYPE-TESTING PROTOCOL		
Doc No: IMD/TP/04b	Version No: 2	Revise before: 15 Jun 2027
Effective date: 15 Jun 2024	Replaces: Annex 2	Page 1 of 2
Approved by:	TL-VAX, date: 10 Jun 2024	UH-PQT, date: 13 Jun 2024
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Standard format for a type-testing protocol

WHO/XXX

IMD-PQS Independent type-testing 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>
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

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