The WHO Prequalification of Male Circumcision Devices Programme

September 2012, Geneva

World Health Organization

The WHO Prequalification of Male Circumcision Devices programme: objectives

- Provide **technical information** to other UN agencies, and WHO Member States and other interested organizations on particular male circumcision Devices.
- **Promote and facilitate access** to safe, appropriate and affordable Male Circumcision (MC) devices of good quality in an equitable manner

The WHO PQMC programme: components

Three main components:

- review of the **application form**;
- review of the **product dossier**, including review of clinical evidence; and
- **inspection** of the manufacturing site(s).

The WHO PQ programme : process

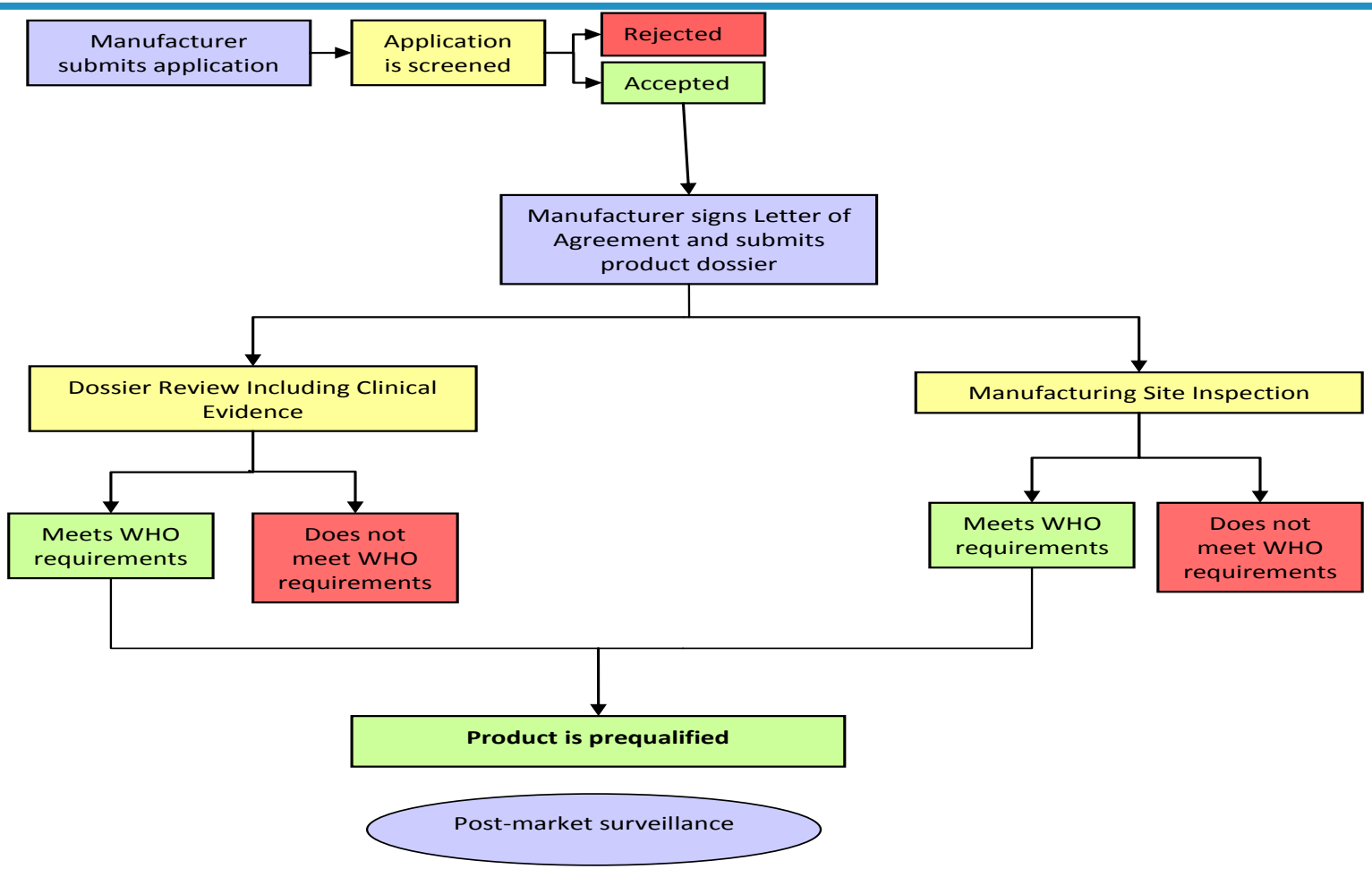

Figure 1: Overview of the prequalification of Male Circumcision Devices process

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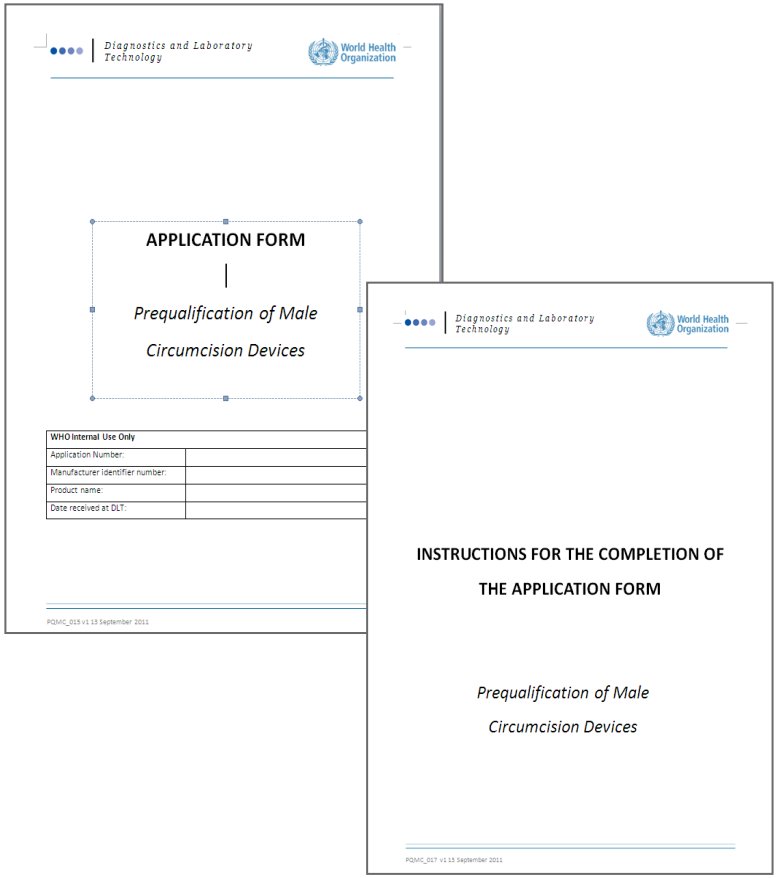
Application to the WHO PQMC programme



The application form provides summary information about

- the MC device product
- the manufacturer

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Product dossier review

- signature of Letter of Agreement → formal request for dossier submission
- Contains **information in support of the submitted application form**
- First screened for completeness → undergoes a full review

Product dossier review

Product dossier = standard technical documentation/ technical file / summary technical documentation / product summary file / product master file

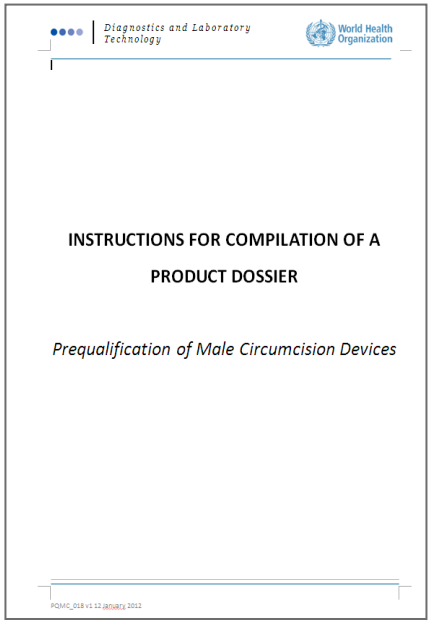
A **selection of records and documents** that shows how the MC device was developed, designed and manufactured

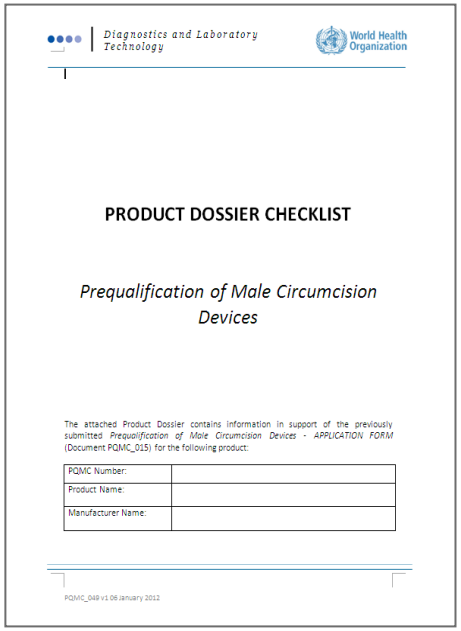
Provides evidence that the MC device conforms to the *Essential Principles of Safety and Performance of Medical Devices* (GHTF/SG1/N41R9:2005)

Product dossier support materials

Product **dossier checklist**

Instructions for compilation of a product dossier (PQDx_018) – based on the GHTF STED for MD





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Product dossier key components

The Product description
Design and Manufacturing Information
Product performance specifications and associated verification and validation
Labeling
Commercial History
Regulatory History
Quality Management System

Manufacturing sites inspection

- WHO inspections programme for medical devices has a global outlook
  - 'stringent' regulatory authorities are for own domestic market
    - may not meet WHO and Global Standards
  - limited regulation in many countries

- Appropriately qualified inspection team:
  - WHO Prequalification programme staff member
  - external experts appointed by WHO
  - inspectors from the National Regulatory Agencies
- The inspection report details identified non-conformances and the required corrective actions

PrePex

When	What
22 Sept 2011	Application for PQ received from Manufacturer.
23 Sept 2011	Application reviewed and accepted.
28 Dec 2011	Agreement letter signed and Dossier requested.
12 Jan 2012	Dossier received from the manufacturer.
17 Jan 2012	Dossier reviewed for completeness and amendments requested.
19 Jan 2012	Site inspection conducted and informal report provided
1 Mar 2012	Final inspection report send to Manufacturer :
3 April 2012	Complete dossier received from Manufacturer.
13 April 2012	Dossier sent for full assessment.
	Awaiting full assessment report due date 15 May 2012.
	Awaiting action plan from Manufacturer.
31 Jul 2012	Full dossier assessment received from reviewer. Site visit planned 23 – 25 October 2012.

ShangRing

21 May 2012	Application for PQ received from Manufacturer.
2 Jul 2012	Application reviewed and additional information requested. Awaiting response from manufacturer.
8 August 2012	EMP re-sent request for information needed from manufacturer to complete application.
21 Sep 2012	EMP awaiting response from manufacturer.

Alisklamp Sterile Disposable Circumcision Device

19 March 2012	Application for PQ received from Manufacturer.
	Application reviewed and additional information requested. Awaiting response from manufacturer
31 Jul 2012	WHO PQ re-sent request for information needed from manufacturer to complete application.
21 Sep 2012	WHO PQ awaiting response from manufacturer to issue letter of agreement

Tara KLamp

Solicited application form Sept 2012

International Standards Organization References

ISO 13485:2003	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO/TR 10013:2001	Guidelines for quality management system documentation
ISO 14971:2007	Medical devices - Application of risk management to medical devices
ISO 14155:2003 parts I and II	Clinical investigation of medical devices for human subjects

Global Harmonization Task Force References

Relevant GHTF guidance	
GHTF/SG1-N63:2011	Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices
GHTF/SG1/N41R9:2005	Essential Principles of Safety and Performance of Medical Devices
GHTF/SG1/N70:2011	Labelling for Medical Devices
GHTF/SG2-N54R8:2006	Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices
GHTF/SG2-N57R8:2006	Medical Devices Post Market Surveillance: Content of Field Safety Notices