



PREQUALIFICATION FEES FOR MALE CIRCUMCISION DEVICES

WHO Prequalification of Male Circumcision Devices

© World Health Organization 2019

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this license, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons license. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the license shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Prequalification fees for Male Circumcision Devices. Version 1 Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

1. Introduction

WHO Prequalification of Male Circumcision Devices undertakes a comprehensive assessment of individual male circumcision devices (MCDs) through a standardized procedure aimed at determining if the product meets WHO prequalification requirements. In addition, once a product is prequalified, WHO assesses all reportable changes to verify that the product continues to meet WHO prequalification requirements.

This document provides information on the fees associated with WHO prequalification of MCDs, and the payment process thereof. There are three types of fees associated with WHO prequalification:

- A prequalification assessment fee per product;
- An annual fee per product; and
- A change assessment fee per product.

The abovementioned prequalification assessment, annual and change assessment fees are non-refundable, and cover in part the cost incurred by WHO in connection with the prequalification process.

Manufacturers should note that WHO reserves the right to decide, based on the prequalification assessment and change assessment findings, whether a product meets the applicable WHO requirements to be prequalified and/or whether to accept a change.

Payment of the prequalification assessment, the annual and/or the change assessment fees does not guarantee that the product will be prequalified, or that a prequalified product will maintain its WHO-prequalified status, or that the change will be accepted.

The section “Exemption from fees” provides details of the categories of changes which are exempt from change fees.

2. Intended audience

This document has been prepared to provide manufacturers with detailed information on the fees applicable to WHO prequalification of MCDs and the payment process thereof.

3. Prequalification assessment fee per product and payment process

The prequalification assessment fee is charged to a manufacturer once its application has been determined as eligible for WHO prequalification assessment.

The prequalification assessment fee will contribute to cover part of the costs associated with product dossier screening, product dossier review, manufacturing site(s) inspection, review of labelling and dissemination of prequalification information.

The following fees apply to applications accepted for WHO prequalification of MCDs assessment:

- For applications undergoing a prequalification assessment: US\$ 5 000 for dossier screening and US\$ 12 000 for product assessment, per product¹.

WHO will issue an invoice to the manufacturer to request payment of the prequalification assessment fee. The prequalification assessment process will not commence unless WHO has first received the full amount of the applicable prequalification assessment fee as well as written evidence of payment thereof. Failure to pay the prequalification assessment fee within the defined timelines will result in cancellation of the application.

Payment of the prequalification assessment fee does not, however, guarantee that the product will be prequalified by WHO.

4. Change assessment fee per product and payment process

WHO will review the change documentation² submitted by the manufacturer to determine the type and level of assessment required which, in turn, will determine whether change assessment fees are charged. When applicable, the change assessment fee is US\$ 3 000 paid in one instalment.

The change assessment fee will contribute to cover the costs associated with the change assessment and dissemination of the change information.

WHO will issue an invoice to the manufacturer to request payment of the change assessment fee. The change assessment process will not commence unless WHO has first received the full amount of the change assessment fee as well as written evidence of the payment thereof. Failure to pay the change assessment fee within the defined timelines will result in cancellation of the change request application.

Payment of the change assessment fee does not, however, guarantee that the product will be prequalified or the change accepted by WHO.

4.1 Exemption of change assessment fees

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_25288

