



TEMPLATE

STANDARD LETTER A - NOTIFICATION OF PRODUCT REMOVAL

Doc No: IMD/TP/11a Version No: 2 Revise before: 15 Nov 2027

Effective date: 15 Nov 2024 Replaces: Annex 1 Page 1 of 2

Approved by: TL-VAX, date: 31 Oct 2024 UH-PQT, date: 31 Oct 2024

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Dear Sir/Madam,

Notification of loss of prequalification status for a product or device listed on the IMD-PQS database.

Your reference:

We refer to <product/device description> which is currently listed on the IMD-PQS database.

We regret to inform you that a decision has been made to remove the product from the database for the following reasons:

EITHER (ref 5.2.1 - unsatisfactory product): <briefly list principle reasons>

You are free to re-submit a new or modified product/device at any time in the future provided it complies fully with the requirements set out in the IMD-PQS performance specification and PQS verification protocol current at the time of re-submission.

OR (ref 5.2.2 – unsatisfactory manufacturer): <briefly list principle reasons>

OR (ref 5.2.3 – major revision to specification or verification protocol):

The reason for this decision is that WHO have revised the IMD-PQS performance specification/verification protocol relating to this class of products and we do not consider that <product/device description> complies with the revised document(s). Accordingly the product will be withdrawn from the database on <dd.mm.yy>. You are free to re-submit a new or modified product/device before that date, or at any time in the future, provided it complies fully with the requirements set out in the revised performance specification/ revised verification protocol, a copy of which we enclose.

OR (ref 5.2.4, 5.2.5 – specification/verification protocol withdrawal/policy change):

The reason for this decision is that WHO have now withdrawn the performance specification relating to this class of products <give reasons if necessary, e.g. policy change>.



**World Health
Organization**

**REGULATION AND PREQUALIFICATION
DEPARTMENT**

VACCINES ASSESSMENT TEAM

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AND:

We regret that we are unable to enter into any [correspondence](#) on this matter.

Yours faithfully,

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