

 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
TEMPLATE		
STANDARD LETTER F - ACCEPTANCE		
Doc No: IMD/TP/09f	Version No: 2	Revise before: 15 Sept 2027
Effective date: 15 Sept 2024	Replaces: Annex 7	Page 1 of 1
Approved by:	TL-VAX, date: 28 Aug 2024	UH-PQT, date: 4 Sep 2024
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Standard letter F - Acceptance

Dear Sis/Madam,

Application for prequalification of a product or device under the IMD-PQS system.

Your reference:

We refer to your application for prequalification dated <dd.mm.yy> concerning <product/device description>.

We have now received the results of the product/device evaluation and are pleased to inform you that <product/device description> has been recommended for inclusion on the database of prequalified products, devices and related services.

We enclose a copy of the evaluation report for your information. You will note that there are certain matters about which the evaluator(s) had concerns. These are as follows:

- <list any items that need to be drawn to the manufacturer's attention>

We hope that you will be able to deal with these matters by the time the product/device is re-evaluated in one year's time.

Finally, we draw your attention again to the terms and conditions set out in the prequalification information pack sent to you on <dd.mm.yy> which apply to all products, devices and services listed in the IMD-PQS database. Note particularly the requirement set out in the performance specification that you inform us of any future changes to the product or device specification or changes to the manufacturing site, and that you notify us of any product recalls, component defects and other events that may affect the product or device.

Yours faithfully,