



TEMPLATE

STANDARD LETTER D - EVALUATION NOTIFICATION

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Standard letter D - Evaluation notification

Dear Sir/Madam,

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

Your reference:

We refer to your letter dated <dd.mm.yy> with regard to <product/device description>, enclosing the Product Dossier requested in our letter dated <dd.mm.yy>.

EITHER:

We have now made a full examination of the Product Dossier and confirm that we consider that the product is suitable for evaluation in accordance with the verification protocol attached to the Prequalification Information Pack. If you wish us to proceed with the evaluation please send us the Product Verification Fee in the sum of <currency><amount>. The verification will be carried out by <name of organization>.

If you have any queries, please contact us as soon as possible.

OR:

We have now made a full examination of the Product Dossier but regret to inform you that we do not consider the product/device is likely to meet the performance criteria set out in the verification protocol attached to the Prequalification Information Pack. The reasons for this are as follows:

- <list reasons>.

You are free to offer 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 IMD-PQS verification protocol current at the time of re-submission.

We regret that we are unable to enter into any further correspondence on this matter.

Yours faithfully,