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In reply please

refer to:

QSS-ND/DM/cj(2013-146)

Mr Boo Sjölin

Smurfit Kappa Lagamill AB

Box 43,

SE-285 21 Markaryd,

Suède

Your reference:

8 May 2013

Dear Mr Sjölin,

## Notice of re-validation for safety box for the disposal of used syringes, needles and sharps

We refer to your safety box "TimSafe 5 L" currently listed in the PQS database as item E010/005.

We would like to thank you for having submitted the complete dossier for revalidation of this item during the 2013 annual review.

We are pleased to inform you that this product is revalidated until 2014 annual review. Accordingly, your safety box will be published under the "*Revalidated devices*" section on the same PQS WHO web page:

http://apps.who.int/immunization\_standards/vaccine\_quality/pqs\_catalogue/

We will notify you formally of the date of next year's review.

Please be aware that although PQS does not explicitly call for active monitoring, we do require notification of adverse events and device failures in accordance with our agreement under the terms and conditions of the PQS prequalification scheme.

Please note that we will inform all UN partners of the prequalification status of your products through a separate letter.

Yours sincerely,

Dr Nora Dellepiane

Scientist

Quality, Safety and Standards