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To whom it might concern

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Dear Sir or Madam,

As a certified medical device company, GME is committed to staying up-to-date with the latest clinical research. We have recently found that scientific literature has identified an additional contraindication and an additional side effect that impacts the scope of your system:

- The additional contraindication is **“No treatment on melanocytic nevi”**
- The additional side effect is **“Paradoxical hypertrichosis”**

During your medical laser education, you were already informed about this contraindication and side-effect. With the patient's safety in mind, we are required to update the user manuals to include the additional contraindication and additional side effect. Please replace your previous user manual with the new revision attached. The new revisions of the user manuals are:

- **User manual LinScan Rev 5 221228**
- **User manual TwinScan Rev 2 221228**

**IMPORTANT NOTE:**

We kindly ask you to confirm that you have replaced the user manual for regulatory reasons. To do so, please reply to this email. You can use the following sample text for this purpose:

*We hereby confirm that we have been informed about the additional contraindication and side effect. We have replaced the user manual with the latest revision.*

We thank you for your assistance in this matter.

Sincerely yours,  
the GME team