

To whom it might concern

Erlangen, 2023-10-09

Dear Sir or Madam,

GME is currently preparing for certification within the new regulatory framework of the Medical Device Regulation (MDR). In case of the FlexSys, we have included additional elements in the user manual that are required by the new regulation. In particular, we have expanded section 3 of the user manual to include the following definitions:

- Target patient group
- Intended use
- Residual risks

Additionally, we have decided to define the minimum age for the target patient group to be 18 years. We selected this minimum age due to the tightened requirements on clinical evidence according to the MDR and lack of clinical studies for patients under 18 years of age. Please note that the contraindication for UVB treatments remains unchanged for patients under 15 years of age.

With the patient's safety in mind, please replace your current user manual with the new revision attached. The new revision of the user manual is:

- **User manual FlexSys Rev 8 221028**

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 replaced the user manual with the latest version.

We thank you for your assistance in this matter.

Sincerely yours,
the GME team