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Date: 12 February 2023

Addressing the issue of foam in Sefam S-Box CPAPs and Bilevels

Sefam Medical Ltd entered the UK market in 2021 with the cutting-edge S-Box CPAP/APAP device and S-Box Duos and ST Bilevel devices. This market entry was instigated through the UK Cabinet office as a result of the global withdrawal of Philips devices because of concern over the type of foam used as has been reported.

As part of the due diligence undertaken by the UK authorities Sefam SAS (Northern France manufacturer) had to supply evidence to the MHRA and the supply authorities specifically on the safety of the noise abatement foam used in the Sefam range of devices. The accompanying letter attached outlines in more technical detail the explanation on the type of foam and the safety testing that foam has undertaken.

Sefam devices are designed, manufactured and under the review of a registered notified body who regularly review issues and recommend remedial actions where necessary.

All Sefam's devices are safe for patients to use daily and for the lifespan of the device when following the instructions for use.

Michael McEwan

Managing Director
Sefam Medical Ltd

Sefam SAS has been manufacturing CPAP devices in Northern France for 40 years and follow the strictest regulatory standards asked for by the European regulatory agencies.