

Official LINET UK Ltd Corporate Statement

07/09/2023

Dear Valued Partners and Stakeholders,

In response to the recent National Patient Safety Alert released by the MHRA, LINET UK Ltd wishes to provide a formal statement regarding our commitment to product compliance with the standards BS EN 60601-2-52:2010+A1:2015 and BS EN 50637:2017.

Here is a concise overview:

BS EN 60601-2-52:2010+A1:2015: These regulations were instituted in 2015. It is imperative to recognise that products manufactured prior to June 2015 may not meet the compliance criteria. Therefore, customers are encouraged to perform risk assessments against action points 5, 6, and 7 outlined in the Safety Alert. All LINET products falling under this Regulation and manufactured after June 2015 are fully compliant.

BS EN 50637:2017: This standard exclusively pertains to the 'TOM 2' product within the LINET Group portfolio. The regulations for BS EN 50637:2017 were officially published in November 2017. To verify compliance for the 'TOM 2' product, kindly reference the model number. Model number 1k4 is deemed compliant, whereas all other model numbers necessitate a comprehensive risk assessment, as they do not conform to the standard.

At LINET UK Ltd, we uphold our commitment to ensuring the highest levels of safety, quality, and compliance for all our products. The trust you place in our dedication to product safety and performance is paramount.

We remain at your disposal for any additional inquiries or clarifications you may require. Your partnership is greatly valued, and we look forward to continuing our collaboration.

Sincerely,

Josef Novacek

Managing Director
LINET UK Ltd

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