Peacocks MEDICAL

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Statement on the Safe Use
of the Snooooooze Sleep System and Little Dots Products

The **Snooooooze Sleep System**, classified as a **Class I Medical Device**, must only be used under the prescription and guidance of a trained clinician or product adviser. Use of this device requires users to be **technically competent** and fully informed of the safety information provided in the accompanying instructions for use.

In compliance with the **EU Medical Device Regulation (MDR) 2017/745**, a comprehensive risk assessment has been conducted for the Snooooooze and Little Dots product range in accordance with **ISO 14971:2019**. This process identified **suffocation** as a potential risk associated with the use of the devices.

Despite all appropriate measures being incorporated into the design to mitigate the risk of suffocation, a **residual risk remains**. It is therefore **imperative** that the Snooooooze and Little Dots systems are used strictly **within their intended purpose**, as **prescribed by the clinician or product advisor**, and in **full compliance** with the instructions provided.

Failure to adhere to the prescribed use and guidance significantly increases the risk of adverse events, including suffocation.

Prior to issuing the Snooooooze or Little Dots products to a client, a **risk assessment** must be completed. The findings of this assessment should be **clearly communicated to parents and carers**, highlighting any potential hazards identified. Furthermore, **appropriate training and ongoing support** must be provided at the point of supply to ensure the safe and effective use of the device.

Document approval and revision history

Rev	Date	Author	Details	Authorised by
01	17 April 2025	L Reeks	Initial Version	L Reeks

Smirthwaite Ltd, 17 Wentworth Road
Heathfield, Newton Abbot, Devon TQ12 6TL

T: +44 (0) 1626 835552
E: info@smirthwaite.co.uk
www.smirthwaite.co.uk