Subject: Understanding Pessary Classification – Why Class Matters

Dear Customer,

Pessary devices for pelvic organ prolapse are classified according to their intended use and duration of use, as set out in UK and EU medical device regulations.

Some pessaries are classified as Class IIa, typically intended for short-term use (up to 30 days). Others, including our own, are classified as Class IIb, intended for long-term use (more than 30 days, including removal and reinsertion).

As per current legislation and regulatory requirements all devices must be used in accordance with their approved indications and duration of use, as set out in the manufacturer's instructions for use. This helps ensure patient safety and compliance.

Class IIb devices undergo more extensive regulatory assessment, including additional biocompatibility and long-term use testing, to support their intended use over extended periods. This ensures robust evidence for safety and performance in long-term applications.

This note is intended to provide general information on regulatory classification for healthcare professionals. For further details or to discuss our range of Class IIb silicone pessaries, please contact us at help@mediplusuk.com.

Yours sincerely,

Mediplus

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