UK Declaration of Conformity

REDWOOD

Technical Textiles & Specialist Manufacturing

We Redwood TTM Ltd 1 Paddock Road, Skelmersdale, Lancashire, England, WN8 9PL, declare that under our sole responsibility the products listed in annex 1 of this document are in conformity with the following UK Regulation:

Regulation SI 2002/618 (Medical Device Regulation)

The product(s) are in conformity with the provisions of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) Medical Device Directive based on the requirements of the relevant Annexes to the European Directive 93/42/EEC on medical devices (EU MDD) as modified by Part II of Schedule 2A of the UK Medical Device Regulations 2002, including fulfilment of the applicable essential health and safety requirements set out in Annex I.

This declaration of conformity is issued under the sole responsibility of the manufacturer.
Signed on behalf of Redwood TTM Ltd.

Stephen Boyd

Compliance Manager

Date: 01.04.2021

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Annex 1

Products

Product	Description
VMS110	Low risk* foam mattress support surface.
VMS120	Low risk* foam mattress support surface.
VMS130	Low risk* foam mattress support surface.
VMS210	Medium risk* foam mattress support surface.
VMS220	Medium risk* foam mattress support surface.
VMS310	High risk* foam mattress support surface.
VMS310-B	High risk* foam mattress support surface.
VMS320	High risk* foam mattress support surface.
VMS330	High risk* foam mattress support surface.
VMS410	Low risk* foam mattress support surface.
VRP100	Low risk* foam mattress support surface.

*Refers to the patient risk of developing pressure ulcers following a clinical evaluation by a suitably qualified professional as part of an overall package of care.

Applied standards and specifications.

ISO 9001:2015	Quality management system requirements
ISO 10993-1:2018	Biological evaluation of medical devices- Evaluation and testing
ISO 10993-5:2009	Biological Evaluation of Medical Devices – in vitro cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Devices -Test for irritation and skin sensitisation
ISO 10993-18:2020	Biological Evaluation of Medical Devices- Chemical characterisation of materials
ISO 14971:2019	Application of risk Management to Medical Devices
BS 7175:1989	The ignitability of bedcovers and pillows when subjected to smouldering and flaming Sources
BS 7177:2008+A12011	Specification for resistance to ignition of mattresses, mattress pads, divans, and bed bases
EN 597-1:2015	Furniture - assessment of the ignitability of mattresses and upholstered bed bases. Ignition source smouldering cigarette
EN 597-2:2015	Furniture - assessment of the ignitability of mattresses and upholstered bed bases. Ignition source: match flame equivalent
BS 6807:2006	Methods of test for assessment of ignitability of mattresses, upholstered divans and upholstered bed bases with flaming types of primary and secondary sources of ignition
ISO 15223-1:2020	Medical devices — Symbols to be used with information to be supplied by the manufacturer— Part1: General requirement