Devon Static Mattresses

INSTRUCTIONS FOR USE

This manual MUST be read BEFORE using this product

Devon Static Mattresses

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1. Introduction

This document outlines important information and instructions for use (IFU) about the safe and effective use of the product. Read all instructions carefully before using the product. Store the IFU in a designated area, where it is always easily accessible. If unsure, consult a medical professional regarding the correct use of the product. For further product-related information, contact Winncare PAC Ltd directly; see the "Contact Information" section of this document.

2. Symbols

Symbols and advisory notices are used in this document to help safe and optimal operation of the product. See information below for definitions of the symbols.

WARNING	**Warning:** Safety warning. Failure to obey and understand could lead to injury to yourself or others, and in some circumstances death.
CAUTION	**Caution** to highlight potential hazards that, if failed to follow, could lead to damage or failure in parts or all of the system and equipment.
NOTE	**Note:** Important information users should be aware of for correct use of the equipment.

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3. Product Labelling

The labels shown are for illustrative purposes only – some symbols on your product may differ from the examples shown.

UK CA	UK marking indicating conformity with UK Medical Device Regulations 2002 (SI 2002 No 8, as amended)	CE	CE marking indicating conformity with European Community harmonized legislation. Figures indicate Notified Body supervision.
	Name and address of the manufacturer	EC REP	Authorized Representative in the European Community
UDI	Unique device identifier	°C °C	Temperature limitation to indicate the temperature limitation for the product during usage
REF	Product Reference Number	MD	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.
LOT	Lot number	SN	Serial Number
	Instructions for Use Read the Instructions for use before use		Date of manufacture
	Recycling	5	Resistant to ignition
	Foot end of mattress		Safe Working load (SWL) is the maximum combined weight of the patient and any equipment that the mattress can safely support.
	Max Patient weight defines the maximum total load of the patient kg		Do not use sharp objects

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	Do not fold. Roll pack the system		Do not use when damp, ensure surface is dry before use
	Do not place heavy objects on surface of cover other than the patient		Ensure system is dry before storing, use and reuse.
	Do not iron	PHENOL	Do not use harsh abrasives or Phenol cleaners
	Tumble dry on a low setting	95°	Machine wash up to 95°C.
Cl 1000 ppm NaOCl NaDCC	Disinfect by wiping the surface using a hypochlorite solution diluted 1000 ppm.		

4. Warnings and Precautions for Use

WARNING

Ensure the device is assembled and operated as intended. RISK OF PRESSURE INJURY.

WARNING

Do not expose any parts of the device to a naked flame. Do not smoke. RISK OF FIRE AND PROPERTY DAMAGE.

WARNING

Ensure the patient is manually repositioned at frequent intervals. RISK OF PRESSURE INJURY.

CAUTION

Perform a risk assessment when pairing devices with medical beds and accessories.

CAUTION

Do not use if device does not fit bed frame. Device performance may be affected.

CAUTION

Device performance may be affected when in use with incontinence products. Complete a risk assessment prior to use.

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5. Product Overview

NOTE	This IFU is only applicable to the variants of the Devon mattresses listed in Technical specification Section of this document. Please ensure this IFU is applicable to your product, otherwise consult a different IFU.

Intended Use	To provide pressure redistribution when used in conjunction with an appropriately sized bed frame and as part of an overall package of care for pressure injury prevention.
Intended Users	Typical adults, adults with atypical anatomy and persons of size, with restricted to limited mobility, undergoing some medical supervision and monitoring in hospital, long-term care or care home settings.
Indications	Suitable for users identified as being at risk to high risk of developing pressure injuries.
Contraindications	Patients below the minimum or above the maximum user weight stated for the associated device.
Users	Caregivers, laypersons and/or medical professionals.
Warranty	2 years subject to regular maintenance and care.
Reusable	Devices are re-usable and must be cleaned between each patient use.
Maintenance or calibration	Perform regular mattress audits to check for foam functionality, fluid ingress and strike-through on the mattress top cover.
Accessories	Devices are not sold with accessories.
Risk Assessment	It is the responsibility of the end user/care provider to carry out the necessary risk assessment to ensure patient safety. This should be carried out before using the mattress. A risk assessment should include, but not be limited to: • Product combinations (bed frame, mattress, side rails etc.) • Extent of tissue damage (if any) • Entrapment • Patient falls • Small adults (and children) • Patients with learning difficulties • Patients with atypical anatomy • Unauthorised people with access to the controls • Use with other medical accessories e.g. incontinence products

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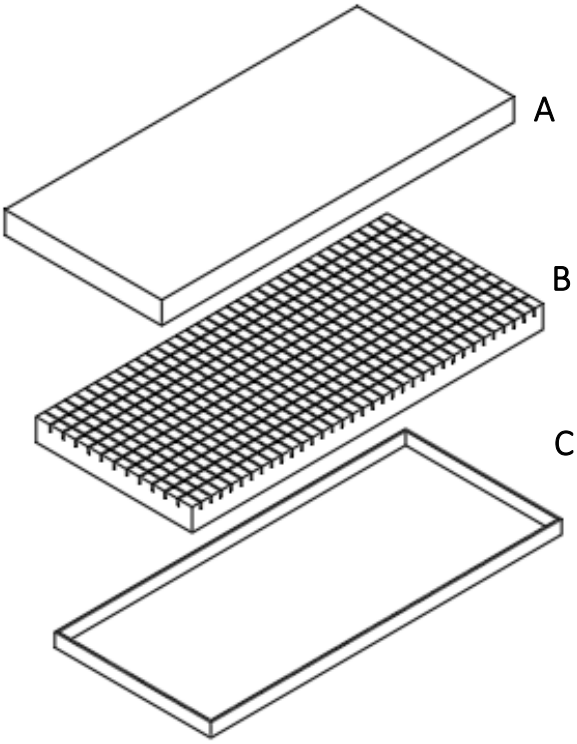
6. Product Description

Devon is a range of high-specification full-replacement static foam mattresses, with side formers (C) that provide additional stability for patient egress and ingress. The range has been developed using the very latest combustion modified ether (CME) foam technology, with the Devon featuring a castellated foam insert (B) that conforms to the patient's body, increasing the surface area in contact with the mattress, through immersion and envelopment. One of our most popular community mattresses, the Devon provides a comfortable surface that protects budgets.



A	Multi-stretch waterproof, antimicrobial, vapour permeable cover
B	Castellated foam mattress
C	Polyurethane base cover

7. Product Installation & Use

7.1 Preparing the Mattress for Use

Rolled mattresses must be allowed to recover before use.

1. Take the mattress to the room it is intended for and remove from packaging. Do this using scissors rather than a knife, taking care not to damage your rolled up mattress while removing the packaging.
   DO NOT USE a blade or Stanley knife as this can easily damage the cover, and the mattress will not be suitable for use.
2. The room should be warm, approx. 20°C. DO NOT USE a hair dryer or leave it too close to portable heaters, as this can cause damage.
3. To provide full support, leave the mattress for at least 24 hours before use.

Mattresses that are delivered flat-wrapped can be used immediately.

7.2 Installation

1. Remove all packaging before use.

NOTE	Ensure the printed side of the mattress cover always faces upwards.

2. Place the mattress directly on the bed frame with the "foot" symbol at the foot end of the bed.

NOTE	Do not grip the mattress by the top cover or the zip flaps when lifting. Winncare recommends performing the lifting step with 2 people wherever possible

3. Ensure the mattress is positioned centrally on the bed frame. If there is excessive movement of the mattress on the bed frame, this could indicate a size incompatibility between the bed frame and the mattress. Do not use.
4. Ensure there are no gaps between the mattress and bed frame/side rails. Perform the necessary risk assessments to mitigate entrapment risk.

NOTE	Ensure the mattress is only used with compatible equipment/accessories.
NOTE	Do not use if mattress is sliding in the bed frame. Reconsider mattress size.
NOTE	Do not use if mattress is tight fitting in the bed frame. Reconsider mattress size
NOTE	Do not drag the mattress, always carry it.

WARNING

Do not remove the mattress from the bed frame if the occupant is still on the mattress. RISK OF FALL.

8. Cleaning & Disinfection

Cleaning and disinfection of the device is mandatory. As a minimum, cleaning and disinfection should be performed before use, between each patient, at regular intervals whilst in use and before being returned to storage. Consult local practice guidelines for more details on cleaning and disinfection of reusable medical devices.

Follow the instructions below to achieve a minimum level of cleaning and disinfection for safe use of the device.

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WARNING

Wear appropriate personal protective equipment (PPE) when cleaning the mattress or control unit. RISK OF SKIN IRRITATION

CAUTION

Do not use phenol-based cleaning solutions, solvents, neat bleach or abrasive products to clean the casing as this may cause damage.

CAUTION

Do not use top cover if strike-through or damage is suspected.

CAUTION

Do not use Phenol-based solutions or abrasive compounds.

CAUTION

Do not autoclave.

8.1 Cleaning & Disinfection Protocol: Mattress

1. Unzip the cover on all sides.
2. Inspect the underside of the cover and the foam mattress for any signs of strikethrough or contamination. If damaged, use a new cover or mattress. Dispose of damaged items as per local protocols.
3. For general cleaning; (if using an existing cover)
    a. Wipe down with a soft, clean, non-abrasive cloth moistened with a mild detergent and diluted in warm water (40˚C).
    b. Rinse with cold, clean water and a fresh, soft, non-abrasive cloth and allow to fully dry before use.
4. For disinfection
    a. Light Soiling: Unzip the top cover from the mattress. The top cover can be machine washed up to 95°C and tumble dried on a cool setting.
    b. Heavy Soiling: Carefully clean with (1,000 ppm) prepared solution of sodium hypochlorite and allow to dry completely. In extreme circumstances 10,000 ppm can be used; wipe with cold water to finish (Frequent cleaning with a high concentration disinfectant solution i.e. 10,000 ppm available chlorine, may reduce the life-span of the device).
5. Reassemble the mattress.
6. Ensure the mattress is completely dry before storage or reuse.

NOTE	Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of the mattress.

NOTE	In the event of contamination, contact your infection prevention and control department. Remove contaminated foams from use.

8.2 Replacing the cover

1. Unzip the cover from the mattress and remove it carefully from the foam inner.
2. Place a new cover onto the foam inner
3. Ensure the foam inner is positioned correctly, with the corners of the foam sitting in the corners of the cover.
4. The castellated foam surface should be facing upwards when inserted into the cover.
5. Close the zip.

9. Storage

Follow the instructions below to prepare the product for storage.

CAUTION

Ensure device is cleaned and disinfected prior to storage.

1. Lay the mattress out flat.
2. Store in a dry environment, sealed in a polythene bag to protect from dirt, debris, fluids etc., with a suitable identification tag.
3. Never store items on top of a device.

NOTE	Do not store near radiators or other sources of heat.
NOTE	Protect the device from direct sunlight.

4. If taking a device out of storage, allow it to acclimatise to the operating conditions.

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10. Care and Preventative Maintenance

The expected service life of this product is five years when used daily and maintained according to the manufacturer's instructions.

Check mattresses (foam and cover) for strike-through (due to fluid ingress, stains, rips or damage) after each patient, after use or every month (depending on which occurs first) by a suitably qualified and competent person.

The effective service life can vary according to the frequency and intensity of use. Winncare PAC Ltd. recommends an annual audit of all foam surfaces. Contact Winncare PAC Ltd to arrange your annual audit. For optimal performance, more frequent visual and operational inspections are encouraged wherever possible.

NOTE	No modification of this equipment is allowed. Use original parts only.

11. Warranty

This product is covered by a two year manufacturer's warranty as part of the General Terms and Conditions of Business.

Any warranty claims during the warranty period must be investigated by Winncare PAC Ltd, where return of the original product may be required. A warranty claim is successful if the product is faulty due to a manufacturing defect. This warranty does not cover any other damage, including but not limited to: misuse, natural wear and tear, lack of maintenance, accidental damage and unauthorised modifications.

12. Disposal

It is recommended the mattress should be disinfected prior to decommissioning. Adhere to local laws and regulations for the safe disposal of medical devices and accessories. If in doubt, contact Winncare PAC Ltd for guidance or to arrange for collection and disposal.

WARNING

Do not dispose in general waste. RISK OF ENVIRONMENTAL CONTAMINATION.

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13. Technical Specifications

Product Code	DEV-113
Product Description	Devon Mattress 1980 x 880 x 150
Dimensions	198 x 88 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-1200W
Product Description	Devon Mattress 1980 x 1200 x 150mm
Dimensions	198 x 120 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-2000X850X140
Product Description	Devon 2000 x 85 x 140 3 Flap Cover
Dimensions	200 x 85 x 14 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	13

Product Code	DEV-113-DIVAN
Product Description	Devon Mattress 1900 x 900 x 150
Dimensions	190 x 90 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric

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Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-E
Product Description	Devon Eco Mattress 1980X880X125 mm
Dimensions	198 x 88 x 12.5 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-E-DIVAN
Product Description	Devon Eco 1900 x 900 x 127mm
Dimensions	190 x 90 x 12.7 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-E-FW
Product Description	Fully Welded Devon Eco 1980x880x125
Dimensions	198 x 88 x 12.5 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Fully Welded (welded only)
Weight (kg)	13

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Product Code	DEV-113-E-FW-V2
Product Description	Fully Welded Devon Eco 1980x1200x125
Dimensions	198 x 120 x 12.5 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Fully Welded (welded only)
Weight (kg)	13

Product Code	DEV-113-E-V11
Product Description	Fully Welded Devon Eco Navy Dacor 1980x1220x125
Dimensions	198 x 122 x 12.5 cm
Top Cover Material	Navy Dacor Polyurethane-coated Polyester fabric
Base Cover Material	Navy Dacor Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Fully Welded (welded only)
Weight (kg)	13

Product Code	DEV-113-E-V12
Product Description	Devon Eco Mattress 1980x880x100mm
Dimensions	198 x 88 x 10 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-E-V2
Product Description	Devon Eco Mattress 2050 x 880 x 125mm
Dimensions	205 x 88 x 12.5 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric

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Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-E-V4
Product Description	Devon Eco Mattress 1900x1350x130
Dimensions	190 x 135 x 13 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-E-V5
Product Description	Devon Eco Mattress 1900x880x125
Dimensions	190 x 88 x 12.5 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-E-V5-FW
Product Description	Fully Welded Devon Eco 1900x880x125
Dimensions	190 x 88 x 12.5 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Fully Welded (welded only)
Weight (kg)	13

Product Code	DEV-113-E-V7

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Product Description	Devon Eco Castellated Mattress 1980x1170x125
Dimensions	198 x 117 x 12.5 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-FW
Product Description	Fully Welded Devon 1980x880x150
Dimensions	198 x 88 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Fully Welded (welded only)
Weight (kg)	13

Product Code	DEV-113-S1
Product Description	Devon Mattress 1900x900x230 3 Side Welded
Dimensions	190 x 90 x 23 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	13

Product Code	DEV-113-V11
Product Description	Devon Mattress 1050mm wide
Dimensions	198 x 105 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress

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Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-V12
Product Description	Devon Mattress 1980x1500x150
Dimensions	198 x 150 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-V13
Product Description	Devon With Bookstyle Cover 1800x780x140
Dimensions	180 x 78 x 14 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	13

Product Code	DEV-113-V14
Product Description	Devon Mattress 1920x820x150
Dimensions	192 x 82 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-V15
Product Description	Devon Mattress 1880x880x150mm

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Dimensions	188 x 88 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-V16
Product Description	Devon Mattress 2100x900x150
Dimensions	210 x 90 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-V17
Product Description	Devon Mattress 1900x1370x150 No Print
Dimensions	190 x 137 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-V2
Product Description	Devon Mattress 1840 x 900 x 15
Dimensions	184 x 90 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Devon Static Mattresses

Product Code	DEV-113-V5
Product Description	Devon Mattress 2000x900x203 (8")
Dimensions	200 x 90 x 20.3 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-V6
Product Description	Devon Welded Mattress 1640x900x150
Dimensions	164 x 90 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Fully Welded (welded only)
Weight (kg)	13

Product Code	DEV-113-V7
Product Description	Devon Double Mattress 1980x1400x150
Dimensions	198 x 140 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-V8
Product Description	Devon 1980 x 900 x 150
Dimensions	198 x 90 x 15 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric

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Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

Product Code	DEV-113-WINNCARE
Product Description	Devon Double Mattress 1980x1370x170
Dimensions	198 x 137 x 17 cm
Top Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Base Cover Material	Basic Blue Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Sewn Only
Weight (kg)	13

14. Transport & Operating Conditions

Transport and storage conditions	Store in a cool dry place.

15. Compliance

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
UK MDR 2002: The Medical Devices Regulations 2002 (SI 2002/618), as amended by SI 2019/791 and subsequent legislation.
ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2019 – Medical devices – Application of risk management to medical devices
ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
BS7175:1989 – The Ignitability of Bedcovers and Pillows by Smouldering and Flaming Ignition Sources
BS 597 parts 1&2 – Furniture – Assessment of the Ignitability of Mattresses and Upholstered Bed Bases
BS7177:2008 + A1:2011 Table 1: Medium Hazard Use

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16. Complaints

Users of the devices referenced in this document are encouraged to report any complaints related to product quality, identity, durability, reliability, safety, effectiveness, or performance. Complaints should be directed to either the local distributor or Winncare PAC Ltd, using the contact details provided in the following section.

When submitting a complaint, please include as much relevant information as possible, such as:

- Device name and product code
- Lot number(s)
- Your name and address
- A detailed description of the issue

17. Contact Information

WINNCARE PAC Ltd.
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NOTE	Inform the competent authority if you believe or have reason to believe that the device presents a serious risk or that it has been tampered with. All serious incidents which are related to the device must be notified to the manufacturer and the competent authority of the member state in which the user and/or patient resides.