



MAKING CARE EASIER



UK Declaration of Conformity

Prism Medical Slings

(DoC details sling purchased by Drive DeVilbiss Healthcare Ltd only)

Technical file Reference: PMUK_TF002

Revision: 1

In Conformance with Medical Devices Regulation (UK) 2002, as amended

Legal Manufacturer	Prism Medical UK Unit 1, Tir Llwyd Industrial Estate, St Asaph Avenue, Kinmel Bay, Rhyl, Conwy, LL18 5JZ, UK
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We hereby declare that the products mentioned below and detailed in the attached appendix meet the provisions of the UK Medical Device Regulation 2002, as amended and Council Directive 93/42/EEC covering medical devices. All documentation is controlled and retained on company premises.

Product Name/type	Care-Ability Slings
Product Models	Full List of Product Codes or Ref. to Product Range Table in appendix 1
Basic UDI-DI	50564089PMUK001RG
Intended use:	Intended to be used with hoist systems for the transfer of clients from one surface to another
GMDN:	38869 - Patient lifting system hammock sling
Classification	Class I – as per Rule 1 in accordance with Schedule 9 of the UK MDR 2002, as amended
Condition supplied:	Non-sterile
Conformity Assessment Route	Conformity assessment based on quality management system on assessment of technical documentation, in accordance with Schedule 10 – the UK MDR 2002, as amended
Applied Directives	UK MDR 2002 UK Medical device Regulation 2013/172/EU Unique Device Identification (UDI)
Applied Standards	EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 15223-1:2021 ISO 20417:2021 ISO 10535:2021 EN 60601-1:2006+ A2:2021
Approved Body	N/A – Class I, self-certified devices.
Identification of Certificate(s)	EC Quality Management System issued by NQA Certificate No. 67420, expiry date: 27 Sept 2024

This declaration of conformity is issued under the sole responsibility of the legal Manufacturer and was written in accordance with Schedule 6 of the UK Medical Device Regulation 2002, as amended and Annex IX of the Council Directive 93/42/EEC. This declaration is supported by the Quality System approval to ISO 13485 issued by NQA. It is a live document and is regularly updated. Unless an update is triggered by a change, this document will expire 5 years after it has been signed.

Identification of the person
authorized to sign on behalf of
Legal Manufacturer:

Name: **William Gray**

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William Gray
Group Lead for Regulatory Affairs

Appendix 1

List of Products

PM Product Code	Drive Product Code	Description
1201HZ7200DR	UNIVERSAL/P/XL	Drive Devilbiss Uni Sling (XL)
1201HZ7220DR	UNIVERSAL/P/HS/ XL	Drive Devilbiss Uni with Head Support (XL)
1201HZ7300DR	UNIVERSAL/P/L	Drive Devilbiss Uni Sling (L)
1201HZ7320DR	UNIVERSAL/P/HS/ L	Drive Devilbiss Uni with Head Support (L)
1201HZ7400DR	UNIVERSAL/P/M	Drive Devilbiss Uni Sling (M)
1201HZ7420DR	UNIVERSAL/P/HS/ M	Drive Devilbiss Uni with Head Support (M)
1201HZ7500DR	UNIVERSAL/P/S	Drive Devilbiss Uni Sling (S)
1201HZ7520DR	UNIVERSAL/P/HS/ S	Drive Devilbiss Uni with Head Support (S)
1201HZ8200DR	UNIVERSAL/M/XL	Drive Devilbiss Uni Sling (XL) Mesh
1201HZ8220DR	UNIVERSAL/M/HS /XL	Drive Devilbiss Uni with HSupport (XL) Mesh
1201HZ8300DR	UNIVERSAL/M/L	Drive Devilbiss Uni Sling (L) Mesh
1201HZ8320DR	UNIVERSAL/M/HS /L	Drive Devilbiss Uni with HSupport (L) Mesh
1201HZ8400DR	UNIVERSAL/M/M	Drive Devilbiss Uni Sling (M) Mesh
1201HZ8420DR	UNIVERSAL/M/HS /M	Drive Devilbiss Uni with HSupport (M) Mesh
1201HZ8500DR	UNIVERSAL/M/S	Drive Devilbiss Uni Sling (S) Mesh
1201HZ8520DR	UNIVERSAL/M/HS /S	Drive Devilbiss Uni with HSupport (S) Mesh
1201PN7200DR	HAMMOCK/P/XL	Drive Devilbiss Hammock Sling (XL) Polyester
1201PN7220DR	HAMMOCK/P/HS/ XL	Drive Devilbiss Hammock with HSupport (XL) Poly
1201PN7300DR	HAMMOCK/P/L	Drive Devilbiss Hammock Sling (L) Polyester
1201PN7320DR	HAMMOCK/P/HS/ L	Drive Devilbiss Hammock with HSupport (L) Poly
1201PN7400DR	HAMMOCK/P/M	Drive Devilbiss Hammock Sling (M) Polyester
1201PN7420DR	HAMMOCK/P/HS/ M	Drive Devilbiss Hammock with HSupport (M) Poly
1201PN7500DR	HAMMOCK/P/S	Drive Devilbiss Hammock Sling (S) Polyester
1201PN7520DR	HAMMOCK/P/HS/ S	Drive Devilbiss Hammock with HSupport (S) Poly
1201PN8200DR	HAMMOCK/M/XL	Drive Devilbiss Hammock Sling (XL) Mesh
1201PN8220DR	HAMMOCK/M/HS /XL	Drive Devilbiss Hammock with HSupport (XL) Mesh
1201PN8300DR	HAMMOCK/M/L	Drive Devilbiss Hammock Sling (L) Mesh
1201PN8320DR	HAMMOCK/M/HS /L	Drive Devilbiss Hammock with HSupport (L) Mesh
1201PN8400DR	HAMMOCK/M/M	Drive Devilbiss Hammock Sling (M) Mesh

PM Product Code	Drive Product Code	Description
1201PN8420DR	HAMMOCK/M/HS /M	Drive Devilbiss Hammock with HSupport (M) Mesh
1201PN8500DR	HAMMOCK/M/S	Drive Devilbiss Hammock Sling (S) Mesh
1201PN8520DR	HAMMOCK/M/HS /S	Drive Devilbiss Hammock with HSupport (S) Mesh
1201WL7200DR	TOILET/P/XL	Drive Devilbiss Toilet Access Sling (XL)
1201WL7220DR	TOILET/P/HS/XL	Drive Devilbiss Toilet with Head Support (XL)
1201WL7300DR	TOILET/P/L	Drive Devilbiss Toilet Access Sling (L)
1201WL7320DR	TOILET/P/HS/L	Drive Devilbiss Toilet with Head Support (L)
1201WL7400DR	TOILET/P/M	Drive Devilbiss Toilet Access Sling (M)
1201WL7420DR	TOILET/P/HS/M	Drive Devilbiss Toilet with Head Support (M)
1201WL7500DR	TOILET/P/S	Drive Devilbiss Toilet Access Sling (S)
1201WL7520DR	TOILET/P/HS/S	Drive Devilbiss Toilet with Head Support (S)
2002MAPB2	PTBXL	AMBITURN/DELUXE POSITIONING BELT XL
2002MAPB3	PTBL	AMBITURN/DELUXE POSITIONING BELT L
2002MAPB4	PTBM	AMBITURN/DELUXE POSITIONING BELT M
2002MAPB5	PTBS	AMBITURN/DELUXE POSITIONING BELT S
CA300DXPP	320	Universal Sling - Polyester Paediatric 1-5
CA300DXPXS	3201XBE	Universal Sling - Polyester Extra Small
CA300DXPS	3201BE	Universal Sling - Polyester Small
CA300DXPM	3202BE	Universal Sling - Polyester Medium
CA300DXPL	3203BE	Universal Sling - Polyester Large
CA300DXPXL	3203XBE	Universal Sling - Polyester Extra Large
CA300DXMP	320	Universal Sling - Mesh Paediatric 1-5
CA300DXMXS	3204XBE	Universal Sling - Mesh Extra Small
CA300DXMS	3204BE	Universal Sling - Mesh Small
CA300DXMM	3205BE	Universal Sling - Mesh Medium
CA300DXML	3206BE	Universal Sling - Mesh Large
CA300DXMXL	3206XBE	Universal Sling - Mesh Extra Large
CA400DXPP	330	Universal Deluxe Sling - Polyester Paediatric 1-5
CA400DXPXS	3301XBE	Universal Deluxe Sling - Polyester Extra Small
CA400DXPS	3301BE	Universal Deluxe Sling - Polyester Small
CA400DXPM	3302BE	Universal Deluxe Sling - Polyester Medium
CA400DXPL	3303BE	Universal Deluxe Sling - Polyester Large
CA400DXPXL	3303XBE	Universal Deluxe Sling - Polyester Extra Large
CA400DXMP	330	Universal Deluxe Sling - Mesh Paediatric 1-5
CA400DXMXS	3304XBE	Universal Deluxe Sling - Mesh Extra Small
CA400DXMS	3304BE	Universal Deluxe Sling - Mesh Small
CA400DXMM	3305BE	Universal Deluxe Sling - Mesh Medium
CA400DXML	3306BE	Universal Deluxe Sling - Mesh Large
CA400DXMXL	3306XBE	Universal Deluxe Sling - Mesh Extra Large
CA500DXPP	310	Toilet / Dress Sling Polyester Paediatric 1-5
CA500DXPXS	3101XBE	Toilet / Dress Sling Polyester Extra Small

PM Product Code	Drive Product Code	Description
CA500DXPS	3101BE	Toilet / Dress Sling Polyester Small
CA500DXPM	3102BE	Toilet / Dress Sling Polyester Medium
CA500DXPL	3103XBE	Toilet / Dress Sling Polyester Large
CA500XPXL	3103XBE	Toilet / Dress Sling Polyester Extra Large
CA500DXMP	310	Toilet / Dress Sling - Mesh Paediatric 1-5
CA500DXMXS	310	Toilet / Dress Sling - Mesh Extra Small
CA500DXMS	310	Toilet / Dress Sling - Mesh Small
CA500DXMM	310	Toilet / Dress Sling - Mesh Medium
CA500DXML	310	Toilet / Dress Sling - Mesh Large
CA500XMXL	310	Toilet / Dress Sling - Mesh Extra Large
CA600DXPXS	360	Hammock Sling - Polyester Extra Small
CA600DXPS	360	Hammock Sling - Polyester Small
CA600DXPM	360	Hammock Sling - Polyester Medium
CA600DXPL	360	Hammock Sling - Polyester Large
CA600DXPXL	360	Hammock Sling - Polyester Extra Large
CA600DXMXS	3601XBE	Hammock Sling - Mesh Extra Small
CA600DXMS	3601BE	Hammock Sling - Mesh Small
CA600DXMM	3602BE	Hammock Sling - Mesh Medium
CA600DXML	3603BE	Hammock Sling - Mesh Large
CA600DXMXL	3603XBE	Hammock Sling - Mesh Extra Large
CA700DXPP	340	Classic Hammock Sling - Polyester Paediatric 1-5
CA700DXPXS	3401XBE	Classic Hammock Sling - Polyester Extra Small
CA700DXPS	3401BE	Classic Hammock Sling - Polyester Small
CA700DXPM	3402BE	Classic Hammock Sling - Polyester Medium
CA700DXPL	3403BE	Classic Hammock Sling - Polyester Large
CA700DXPXL	3403XBE	Classic Hammock Sling - Polyester Extra Large
CA700DXMP	340	Classic Hammock Sling - Mesh Paediatric 1-5
CA700DXMXS	3404XBE	Classic Hammock Sling - Mesh Extra Small
CA700DXMS	3404BE	Classic Hammock Sling - Mesh Small
CA700DXMM	3405BE	Classic Hammock Sling - Mesh Medium
CA700DXML	3406BE	Classic Hammock Sling - Mesh Large
CA700DXMXL	3406XBE	Classic Hammock Sling - Mesh Extra Large
CA701DXPP	460	Deluxe Hammock Sling - Polyester Paediatric
CA701DXPXS	4501XBE	Deluxe Hammock Sling - Polyester Extra Small
CA701DXPS	4501BE	Deluxe Hammock Sling - Polyester Small
CA701DXPM	4502BE	Deluxe Hammock Sling - Polyester Medium
CA701DXPL	4503BE	Deluxe Hammock Sling - Polyester Large
CA701DXPXL	4503XBE	Deluxe Hammock Sling - Polyester Extra Large
CA701DXMP	460	Deluxe Hammock Sling - Mesh Paediatric
CA701DXMXS	460	Deluxe Hammock Sling - Mesh Extra Small
CA701DXMS	460	Deluxe Hammock Sling - Mesh Small
CA701DXMM	460	Deluxe Hammock Sling - Mesh Medium
CA701DXML	460	Deluxe Hammock Sling - Mesh Large

PM Product Code	Drive Product Code	Description
CA701DXMXL	460	Deluxe Hammock Sling - Mesh Extra Large
CA703DXSS	4001BE	Split Leg In Chair Hammock Sling - Spacer Small
CA703DXSM	4002BE	Split Leg In Chair Hammock Sling - Spacer Medium
CA703DXSL	4003BE	Split Leg In Chair Hammock Sling - Spacer Large
CA702/1000DXS S	4101BE	Comfort In Chair Hammock Sling - Spacer Small
CA702/1000DXS M	4102BE	Comfort In Chair Hammock Sling - Spacer Medium
CA702/1000DXS L	4103BE	Comfort In Chair Hammock Sling - Spacer Large
CA800DXPL	3903BE	Chest Sling (Stand-aid) - Polyester Large
CA800DXPXL	3904BE	Chest Sling (Stand-aid) - Polyester Extra Large
CA900DXPXS	3901XTBE	Transport Sling (Stand-aid) - Polyester Extra Small
CA900DXPS	3901TBE	Transport Sling (Stand-aid) - Polyester Small
CA900DXPM	3902TBE	Transport Sling (Stand-aid) - Polyester Medium
CA900DXPL	3903TBE	Transport Sling (Stand-aid) - Polyester Large
CA900DXPXL	3903XTBE	Transport Sling (Stand-aid) - Polyester Extra Large
20024DR4200B E	4200BE	Able Assist Patient Transfer Sling – Adjustable

Revision History

Rev Number	Date	Comment	Author
1.0	20 September 2023	Initial issue of DRIVE specific DoC under UK MDR 2002, as amended.	W. Gray