

UKCA Declaration of Conformity.

(This Declaration of Conformity is issued under the sole responsibility of the manufacturer)

Manufacturer:

WSR Medical Solutions, Unit 2 Hargreaves Mill Hargreaves Street Haslingden Lancashire BB4 5RQ United Kingdom

Authorised Representative: N/A

UK Medical Device Regulations 2002 (UK MDR, S.I. 2002/618), as amended, implementing European Directive 93/42/EEC on medical devices (EU MDD), as they apply in Great Britain

This declaration of conformity is issued under the sole responsibility of WSR Medical Solutions Limited, in compliance with Part II of the UK MDR 2002 (as amended), MDD Annex VII. The undersigned declares that the products described in this document meet the relevant Regulation provisions that apply to them and the UKCA Mark may be affixed.

Device name.	Basic UDI-DI	Product code	Purpose of device	Risk class.	SRN	Sterile	Measuring Function
Mattresses – X-Ray Table	See Appendix 1	See Appendix 1	To provide a radiolucent layer of cushioning between the patient and the x-ray table during diagnostic radiological examinations	1		NO	NO
Mattresses - Interventional	See Appendix 1	See Appendix 1	To provide a radiolucent layer of cushioning between the patient and the x-ray table during diagnostic radiological examinations	1		NO	NO

Conformity Assessment Route:

Self-certification by UK Medical Device Regulation 2002 Part II, applying EU MDD Annex VII EC Declaration of Conformity.

Applicable Standards:

Standard / Document	Description
Medical Devices Regulations 2002	Medical Devices Regulations 2002 (S.I. 2002/618) as subsequently amended by the EU Exit Regulations of
	2019 (S.I. 2019/791) and 2020 (S.I. 2020/1478)
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC.
(EU) 2017/745 (Article 120)	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
BS EN ISO 20417:2021	Information supplied by the manufacturer of medical devices.
BS EN ISO 14971:2019+A11:2021	Medical Devices - Application of Risk Management to Medical Devices
BS EN ISO 15223 -1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied.
BS EN ISO 10993 -1:2020	Biological evaluation of medical devices. Part 1. Evaluation and testing within a risk management process

GMDN: 35184

ISSUED BY:

SIGN

NAME: Paul Dixon, DATE:...April 2024



Appendix 1

Product Code UDI-DI Product Code UDI-DI FP47 5057326001384 FPL198 505732600120 FP48 5057326001391 FP97 505732600042 FP67 5057326001407 FP98 5057326000392 FP68 5057326001421 FP478E 505732600305 FP147 5057326001612 FP478E 505732600302 FP147 5057326001612 FP478E 505732600302 FP147 5057326001526 FP476Y 505732600306 FP147 5057326001526 FP488E 505732600306 FP147 5057326001759 FP67BE 505732600306 MATT CUST 5057326003272 FP67RE 5057326003067 MATT CUSTBE 5057326003272 FP67RE 5057326003067 MATT CUSTGY 5057326003295 FP67GY 5057326003067 SIE-MATVFL25WWCFV 5057326001766 FP688E 5057326003104 SIE-MATVFL25WWCFV 5057326001773 FP6487E 5057326003104 SIE-MATGRADSWC 5057326001780 FP1478E	Mattress – X-Ray Table				
FP48 5057326001391 FP97 505732600042 FP67 5057326001407 FP98 505732600059 FP68 505732600141 FP47BE 5057326003005 FP147 5057326001421 FP47KB 5057326003029 FP148 505732600162 FP47KB 5057326003029 FP148 505732600162 FP48KB 505732600303 FP168 505732600179 FP48KB 505732600304 MATT CUST 5057326003272 FP67BE 5057326003074 MATT CUST 5057326003272 FP67KB 5057326003074 MATT CUST 505732600329 FP67G 5057326003074 MATT CUST 505732600329 FP67G 5057326003074 MATT CUST 505732600329 FP67G 5057326003074 SIE-MATYRL25WSCV 5057326001730 FP488B 5057326003081 SIE-MATYRL25WSCV 5057326001730 FP147BE 5057326003120 SIE-MATGREYFL25WWCFV 5057326001737 FP688F 5057326003120 SIE-MATGREYFL25WWCFV 5057326001730 <	Product Code	UDI-DI	Product Code	UDI-DI	
PF67 5057326001407 FP98 5057326002992 FP68 5057326001414 FP47EE 5057326002992 ST1F 5057326001605 FP47EK 5057326003012 FP147 5057326001612 FP47EK 5057326003029 FP148 5057326001629 FP48E 5057326003036 FP168 5057326001629 FP48KB 5057326003043 MATT CUST 505732600159 FP67BE 5057326003050 MATT CUSTE 5057326003272 FP67RE 5057326003067 MATT CUSTE 5057326003289 FP67BE 5057326003074 MATT CUSTKB 5057326003286 FP68KB 505732600308 SIE-MATVEL25WSCV 5057326001766 FP68KB 5057326003140 SIE-MATVEL25WWCFV 5057326001773 FP68KB 5057326003141 SIE-MATVEL25WWCFV 5057326001780 FPL478E 5057326003141 SIE-MATGREYL25WWCF 5057326001780 FPL478E 5057326003142 SIE-MATGREYL25WWCF 5057326001780 FPL478E 5057326003159 SIE-MATGREYL25WWCF	FP47	5057326001384	FPL198	5057326001889	
PF68 5057326001414 FP478E 5057326002992 ST1F 5057326001421 FP47KB 5057326003005 FPL47 5057326001605 FP47GY 5057326003029 FPL48 5057326001612 FP48BE 5057326003029 FPL67 5057326001629 FP48RB 5057326003036 FPL68 5057326001759 FP678E 5057326003050 MATT CUST 5057326003272 FP67KB 5057326003074 MATT CUST 5057326003299 FP678E 5057326003074 MATT CUSTKB 5057326003296 FP688E 5057326003074 MATT CUSTGY 5057326001773 FP686GY 505732600308 SIE-MATVEL2SWVCV 5057326001773 FP68GY 5057326003144 SIE-MATGRYLC2WVCF 5057326001773 FP68GY 5057326003144 SIE-MATGRYLC2WVCF 50573260017780 FP147BE 5057326003142 SIE-MATGRYLC2WVCF 5057326001780 FP147BE 5057326003142 SIE-MATGRYLC2WVCF 5057326001803 FP147GY 5057326003135 SIE-MATGRYLC2WVCF	FP48	5057326001391	FP97	5057326000042	
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SIE-MATGR40GWCV 5057326001827 FPL48KB 5057326003159 FPL1033 5057326001858 FPL48GY 5057326003166 FPL148 5057326001865 FPL67BE 5057326003173 FPL168 5057326001872 FPL67KB 5057326003180 Mattress – Interventional Product Code UDI-DI ANGMAT-2-2150600-50 5057326001643 ANGMAT-3-2950600-50 5057326001711 ANGMAT-2-2150600-75 5057326001650 ANGMAT-3-2950600-75 5057326001728 ATAMAT40 5057326001674 ANGMAT-ARM-500150-50 5057326001742 ANGMAT-2-2950700-75 5057326001681 ATAMATCUST75 5057326003258 ANGMAT03-2950700-50 5057326001698 ATAMATCUST50 5057326003258	SIE-MATGR25GWC	5057326001803	FPL47GY	5057326003135	
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FPL148 5057326001865 FPL67BE 5057326003173 FPL168 5057326001872 FPL67KB 5057326003180 Mattress – Interventional	SIE-MATGR40GWCV	5057326001827	FPL48KB	5057326003159	
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	ANGMAT-2-2950700-75	5057326001681	ATAMATCUST75	5057326003258	
ANGMAT-3-2950700-75 5057326001704 5057326001704	ANGMAT03-2950700-50	5057326001698	ATAMATCUST50	5057326003265	
	ANGMAT-3-2950700-75	5057326001704			