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

Mattress – X-Ray Table			
Product Code	UDI-DI	Product Code	UDI-DI
FP47	5057326001384	FPL198	5057326001889
FP48	5057326001391	FP97	5057326000042
FP67	5057326001407	FP98	5057326000059
FP68	5057326001414	FP47BE	5057326002992
ST1F	5057326001421	FP47KB	5057326003005
FPL47	5057326001605	FP47GY	5057326003012
FPL48	5057326001612	FP48BE	5057326003029
FPL67	5057326001629	FP48KB	5057326003036
FPL68	5057326001636	FP48GY	5057326003043
MATT CUST	5057326001759	FP67BE	5057326003050
MATT CUSTBE	5057326003272	FP67KB	5057326003067
MATT CUSTKB	5057326003289	FP67GY	5057326003074
MATT CUSTGY	5057326003296	FP68BE	5057326003081
SIE-MATVEL25WSCV	5057326001766	FP68KB	5057326003098
SIE-MATFVEL25WWCFV	5057326001773	FP68GY	5057326003104
SIE-MATWHITEFL25WWCWF	5057326001780	FPL47BE	5057326003111
SIE-MATGREYFL2GWCF	5057326001797	FPL47KB	5057326003128
SIE-MATGR25GWC	5057326001803	FPL47GY	5057326003135
SIE-MATGR40GWC	5057326001810	FPL48BE	5057326003142
SIE-MATGR40GWCV	5057326001827	FPL48KB	5057326003159
FPL1033	5057326001858	FPL48GY	5057326003166
FPL148	5057326001865	FPL67BE	5057326003173
FPL168	5057326001872	FPL67KB	5057326003180

Mattress – Interventional			
Product Code	UDI-DI	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	5057326001667	ANGMAT-ARM-500150-50	5057326001735
ANGMAT-2-2950700-50	5057326001674	ANGMAT-ARM-500150-75	5057326001742
ANGMAT-2-2950700-75	5057326001681	ATAMATCUST75	5057326003258
ANGMAT03-2950700-50	5057326001698	ATAMATCUST50	5057326003265
ANGMAT-3-2950700-75	5057326001704		