

EU Declaration of Conformity.

(This EU 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
 SRN: GB-MF-000017973

Authorised Representative: Eurolink Europe Compliance
 Limited
 25 Herbert Place
 Dublin
 D02 AY86
 Republic of Ireland
 SRN: IE-AR-000002852

“The device(s) listed below and on the attachment fulfils the requirement of the Regulations of MDR (EU) 2017/745 which apply to the device.”

Device name.	Basic UDI-DI	Product code	Purpose of device	Risk class.	SRN
Mattresses – X-Ray Table	5057326MATTRESSXRT82	See Appendix 1	To provide a radiolucent layer of cushioning between the patient and the x-ray table during diagnostic radiological examinations	1	GB-MF-000017973
Mattresses - Interventional	5057326MATTRESSITV5Z	See Appendix 1	To provide a radiolucent layer of cushioning between the patient and the x-ray table during diagnostic radiological examinations	1	GB-MF-000017973

RELEVANT HARMONISED STANDARDS: EN ISO 14971:2012, EN ISO 15223-1:2016

GMDN: 35184

EMDN: V080399 - MEDICAL CUSHIONS

RELEVANT COMMON SPECIFICATIONS:

ISSUED BY:

SIGN



NAME: Paul Dixon,
 POSITION: Managing Director
 ON BEHALF OF: WSR Medical Solutions Limited
 PLACE OF ISSUE: Haslingden, Lancashire
 DATE: ...October 2023

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		