

EU Declaration of Conformity.

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

Manufacturer: WSR Medical Solutions,
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Authorised Representative: Eurolink Europe Compliance
Limited
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“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
Perspex Positioning Aids	See Appendix 1	GPSC, SDS, ARML, ARMJ, ARMS	To aid in the positioning of patients during diagnostic radiographic procedures.	1	GB-MF-0000117973
Leg Supports	See Appendix 1	LHLS, FTLS	To aid in the positioning of patients during diagnostic radiographic procedures.	1	GB-MF-0000117973
Sandbags	See Appendix 1	FP82, FP83, FP84 FP85, FP86, FP88 FP89	To aid in the positioning of patients during diagnostic radiographic procedures.	1	GB-MF-0000117973
Wipeable Cover Foam Positioning Products	See Appendix 1	FP02Z – FP62Z	To aid in the positioning of patients during diagnostic radiographic procedures.	1	GB-MF-0000117973
Coated Foam Positioning products	See Appendix 1	FP02C – FP62C	To aid in the positioning of patients during diagnostic radiographic procedures.	1	GB-MF-0000117973
Plain Foam Positioning Products	See Appendix 1	FP02 – FP62	To aid in the positioning of patients during diagnostic radiographic procedures.	1	GB-MF-0000117973
Closed Cell Foam Positioning Products	See Appendix 1	FP02L – FP62L	To aid in the positioning of patients during diagnostic radiographic procedures.	1	GB-MF-0000117973

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

GMDN: 58878

EMDN: Z12011280 – PATIENT POSITIONING INSTRUMENTS – HARDWARE ACCESSORIES

RELEVANT COMMON SPECIFICATIONS:

ISSUED BY:

SIGN



NAME: Paul Dixon,

DATE:....December 2021

APPENDIX 1

Perspex Positioning Aids	
Product Code	UDI-DI
SDS	5057326002848
SPSJ	5057326002855
SPSL	5057326002862
SPSC	5057326002879

Leg Supports	
Product Code	UDI-DI
LHLS	5057326001476
FTLS	5057326001483
GPFC354	5057326002763
GPFC243	5057326002770
GPFC354D	5057326002787

Sandbags	
Product Code	UDI-DI
FP82	5057326002916
FP83	5057326002923
FP84	5057326002930
FP85	5057326002947
FP86	5057326002954
FP88	5057326002961
FP89	5057326002978

Plain Foam Positioning Products					
Product Code	UDI-DI	Product Code	UDI-DI	Product Code	UDI-DI
		FP21	5057326000639	FP20	5057326000615
FP02	5057326000103	FP21U	5057326000646	FP44	5057326001018
FP03	5057326000141	FP22	5057326000660	FP45	5057326001025
FP04	5057326000189	FP23	5057326000677	FP46	5057326001063
FP05	5057326000226	FP24	5057326000684	FP47	5057326001100
FP06	5057326000264	FP25	5057326000714	FP48	5057326001117
FP07	5057326000301	FP26	5057326000738	FP51	5057326001124
FP08	5057326000325	FP27	5057326000769	FP57	5057326001131
FP09	5057326000349	FP28	5057326000776	FP62	5057326001162
FP10	5057326000387	FP29	5057326000783	FP62U	5057326001179
FP11	5057326000417	FP29U	5057326000806	FP63	5057326001193
FP11A	5057326000424	FP30	5057326000820	FP65	5057326001230
FP12	5057326000448	FP31	5057326000844	FP66	5057326001247
FP13	5057326000462	FP32	5057326000868	FP69	5057326001308
FP14	5057326000486	FP33	5057326000882	FP71	5057326001346
FP15	5057326000493	FP34	5057326000905	FP75	5057326001353
FP16	5057326000516	FP35	5057326000929	FP76	5057326001360
FP17	5057326000530	FP36	5057326000943	FP78	5057326001377
FP18	5057326000554	FP42	5057326000998		
FP19	5057326000585	FP43	5057326001001		

Coated Foam Positioning Products			
Product Code	UDI-DI	Product Code	UDI-DI
		FP18C	5057326000561
FP02C	5057326000110	FP19C	5057326000592
FP03C	5057326000158	FP20C	5057326000622
FP04C	5057326000196	FP24C	5057326000691
FP05C	5057326000233	FP25C	5057326000721
FP06C	5057326000271	FP26C	5057326000745
FP07C	5057326000318	FP29C	5057326000790
FP08C	5057326000332	FP30C	5057326000837
FP09C	5057326000356	FP31C	5057326000851
FP10C	5057326000394	FP34C	5057326000912
FP13C	5057326000479	FP45C	5057326001032
FP15C	5057326000509	FP46C	5057326001070
FP16C	5057326000523	FP58REC	5057326001155

FP17C	5057326000547	FP63C	5057326001209
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Closed Cell Foam Positioning Products			
Product Code	UDI-DI	Product Code	UDI-DI
FP02L	5057326000066	FP39L	5057326000967
FP03L	5057326000127	FP40L	5057326000974
FP04L	5057326000165	FP41L	5057326000981
FP05L	5057326000202	FP45L	5057326001049
FP06L	5057326000240	FP46L	5057326001087
FP09L	5057326000288	FP63L	5057326001216
FP11L	5057326000363	FP66L	5057326001261

Wipeable Cover Foam Positioning Products					
Navy Dartex		Berry Dartex		Grey Dartex	
Product Code	UDI-DI	Product Code	UDI-DI	Product Code	UDI-DI
FP02Z	5057326000134	FP02ZBE	5057326002022	FP02ZGY	5057326002268
FP03Z	5057326000172	FP03ZBE	5057326002039	FP03ZGY	5057326002275
FP04Z	5057326000219	FP04ZBE	5057326002046	FP04ZGY	5057326002282
FP05Z	5057326000257	FP05ZBE	5057326002053	FP05ZGY	5057326002299
FP06Z	5057326000295	FP06ZBE	5057326002060	FP06ZGY	5057326002305
FP09Z	5057326000370	FP09ZBE	5057326002077	FP09ZGY	5057326002312
FP10Z	5057326000400	FP10ZBE	5057326002084	FP10ZGY	5057326002329
FP12Z	5057326000455	FP12ZBE	5057326002091	FP12ZGY	5057326002336
FP18Z	5057326000578	FP18ZBE	5057326002107	FP18ZGY	5057326002343
FP19Z	5057326000608	FP19ZBE	5057326002114	FP19ZGY	5057326002350
FP21Z	5057326000653	FP21ZBE	5057326002121	FP21ZGY	5057326002367
FP24Z	5057326000707	FP24ZBE	5057326002138	FP24ZGY	5057326002374
FP26Z	5057326000752	FP26ZBE	5057326002145	FP26ZGY	5057326002381
FP29Z	5057326000813	FP29ZBE	5057326002152	FP29ZGY	5057326002398
FP32Z	5057326000875	FP32ZBE	5057326002169	FP32ZGY	5057326002404
FP33Z	5057326000899	FP33ZBE	5057326002176	FP33ZGY	5057326002411
FP35Z	5057326000936	FP35ZBE	5057326002183	FP35ZGY	5057326002428
FP36Z	5057326000950	FP36ZBE	5057326002190	FP36ZGY	5057326002435
FP45Z	5057326001056	FP45ZBE	5057326002206	FP45ZGY	5057326002442
FP46Z	5057326001094	FP46ZBE	5057326002213	FP46ZGY	5057326002459
FP63Z	5057326001223	FP63ZBE	5057326002220	FP63ZGY	5057326002466
FP66Z	5057326001278	FP66ZBE	5057326002237	FP66ZGY	5057326002473
FP69Z	5057326001339	FP69ZBE	5057326002244	FP69ZGY	5057326002480
FP62Z	5057326002008	FP62ZBE	5057326001971	FP62ZGY	5057326001988
PCBR	5057326002824				
PPCH	5057326002831				