

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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“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
Mobile Screens	See Appendix 1	MS1L, MS5L,MS1Y,MS5Y	Mobile Radiation Protection devices for the protection of operators / medical staff during ionising radiation procedures.	1	GB-MF-0000117973
Ultimax Table End Shield	5057326001896	TS06	Table Mounted Radiation Protection Devices for the protection of operators / medical staff during ionising radiation procedures.	1	GB-MF-0000117973
Under-Couch Table Shield	5057326000011	TS04	Table Mounted Radiation Protection Devices for the protection of operators / medical staff during ionising radiation procedures.	1	GB-MF-0000117973
Multi Use Table Shield	5057326000028	TS03	Table/Bed Mounted Radiation Protection Devices for the protection of operators / medical staff during ionising radiation procedures.	1	GB-MF-0000117973
Urology Screen (Operating Theatre)	5057326000035	TS02	Operating Table Mounted Radiation Protection Devices for the protection of operators / medical staff during ionising radiation procedures.	1	GB-MF-0000117973
Table Valence	5057326001902	TS05	Table Mounted Radiation Protection Devices for the protection of operators / medical staff during ionising radiation procedures.	1	GB-MF-0000117973
Scatter Shield	5057326000004	RPAB7030	Table Mounted Radiation protection device for the protection of operators / medical staff during ionising radiation procedures.	1	GB-MF-0000117973

RELEVANT HARMONISED STANDARDS: IEC 61331-1:2014, 61331-3:2014, EN ISO 14971:2012, EN ISO 15223-1:2016

GMDN:38373

EMDN: T0399 PROTECTION DEVICES

RELEVANT COMMON SPECIFICATIONS:

ISSUED BY:

SIGN



NAME: Paul Dixon,

DATE:...December 2021

Appendix 1

Mobile Screens		
Product Description	Product Code	UDI-DI
Mobile Screen - Single 0.5LE	MS5Y	5057326001490
Mobile Screen - Single 1.0LE	MS1Y	5057326001506
Mobile Screen - Double 0.5LE	MS1L	5057326001513
Mobile Screen - Double 1.0LE	MS5L	5057326001520