

EU Declaration of Conformity

Imaging Solution (MFG), the exclusive manufactures of RadSafe branded apparel and drapes, declare and assume sole responsibility for manufacturing and distribution of Radiation Protection Equipment and accessories which provides protection from specified ionising radiation and scatter radiation (x-rays).

These Personal Radiation Protective Equipment and Accessories include the following apparel types:

2 Piece Aprons – Vest and Skirt Apron with a lead (Pb) equivalent of either (including in combination) for front and back protection of 0.25mm (minimum), 0.35mm and 0.5mm.

RAD-AP-SK	RadSafe Skirt Only
RAD-AP-VE	RadSafe Vest Only
RAD-AP-VE-BR	RadSafe Back Relief Vest Only
RAD-AP-VE-BR-FO	RadSafe Back Relief Full Overlap Vest Only
RAD-AP-VE-FB	RadSafe Comfortwear Vest Only
RAD-AP-VE-FO	RadSafe Full Overlap Vest
RAD-AP-VE-RV	RadSafe Reverse Vest Only
RAD-AP-VS	RadSafe Best and Skirt w/ Thyroid Collar
RAD-AP-VS-BR	RadSafe Back Relief Vest and Skirt w/ Thyroid Collar
RAD-AP-VS-FB	RadSafe Comfortwear Vest and Skirt w/ Thyroid Collar
RAD-AP-VS-RV	RadSafe Reverse Vest and Skirt w/Thyroid Collar

1 Piece Front Only – Comfort Wear Apron Vest and Skirt Apron with lead (Pb) equivalent of 0.25mm (minimum), 0.35mm and 0.50mm.

RAD-AP-BA	RadSafe Buckle Apron w/ Thyroid Collar
RAD-AP-BR	RadSafe Back Relief Apron w/ Thyroid Collar
RAD-AP-FB	RadSafe Comfortwear Apron w/ Thyroid Collar
RAD-AP-SD	RadSafe Surgical Drop-Off w/ Thyroid Collar
RAD-AP-TA	RadSafe Tie Apron w/ Thyroid Collar
RAD-AP-UA	RadSafe Urology Apron w/ Thyroid Collar

1 Piece Front and Back – Wrap Around Apron lead (Pb) with equivalent of either (including in combination) for front and back protection of 0.25mm (minimum), 0.35mm and 0.50mm.

RAD-AP-MA	RadSafe Maternity Apron w/Thyroid Collar
RAD-AP-SM	RadSafe Smock Apron w/ Thyroid Collar
RAD-AP-WA	RadSafe Wrap Around w/ Thyroid Collar
RAD-AP-WA-BR	RadSafe Back Relief Wrap Around w/ Thyroid Collar
RAD-AP-WA-BR-FO	RadSafe Full Overlap Back Relief Wrap Around w/ Thyroid Collar
RAD-AP-WA-FO	RadSafe Full Overlap Wrap Around w/ Thyroid Collar

Thyroids

RAD-AC-TC-CT	RadSafe Thyroid Collar – Contoured Fit
RAD-AC-TC-MN	RadSafe Thyroid Collar - Mandarin
RAD-AC-TC-ST	RadSafe Thyroid Collar – Straight Fit
RAD-AC-TC-VS	RadSafe Thyroid Collar - Visor

Guards

RAD-AC-SG	Shin Guards
RAD-AC-AG	Shoulder Guard

Smart Caps

RAD-AC-CP	Smart Caps
-----------	------------

Sleeves

RAD-AC-AS	Arm Sleeve
-----------	------------

The declaration of conformity with the provisions of the (EU) Regulation 2016/425 of the European Parliament and of the Council on PPE and, where such is the case, to meet the Manufacturer's Specifications, IEC 61331-1:2014 and IEC 61331-3:2014 is identical to the PPE which is the subject of the EC Type-Examination Certificate No. SH00127 issued by Shirley, Notified Body 2895, Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI.

The item is subject to the conformity assessment procedure set out in the EC Quality System Certificate (Module D) Certificate Number: SH00038 originally under the surveillance of the notified body Shirley, Notified Body 2895 Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI.

Drapes

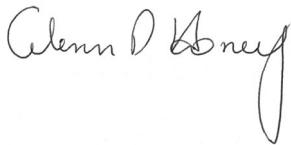
RAD-DP-MPD-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Multipurpose 300mm x 430mm
RAD-DP-MRF-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Multipurpose 300mm x 430mm with fenestration 90mm x 50mm
RAD-DP-MSF-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Multipurpose 300mm x 430mm with scoop fenestration (side) 90mm x 4.5mm
RAD-DP-MCF-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Multipurpose 300mm x 430mm with scoop fenestration (centre) 90mm x 4.5mm
RAD-DP-BSS-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Biliary Split Shield 300mm x 430mm with slit
RAD-DP-FEA-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Femoral Entry

	Angiopathy 300mm x 430mm with 40mm hole and slit
RAD-DP-MPD-250-BLK	RADdrape [®] Non-sterile Radiation Attenuation Drape - Multipurpose 300mm x 430mm
RAD-DP-MSF-250-BLK	RADdrape [®] Sterile Radiation Attenuation Drape - Multipurpose 300mm x 430mm with scoop fenestration (side) 90mm x 4.5mm
RAD-DP-FEA-250-BLK	RADdrape [®] Sterile Radiation Attenuation Drape - Femoral Entry Angiopathy 300mm x 430mm with 40mm hole and slit

The declaration of conformity with the provisions of the (EU) Regulation 2016/425 of the European Parliament and of the Council on PPE and, where such is the case, to meet the Manufacturer's Specifications. These drape products listed above have radiation protective qualities as defined by IEC 61331-1:2014 which is the subject to the upcoming Type-Examination Certificate conducted by Shirley, Notified Body 2895, Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI.

The item is subject to the conformity assessment procedure conformity to type based on quality assurance of the production process (Module D) to be conducted by the Approved Body Shirley, 2895.

Signed for and on behalf of Imaging Solutions (MFG) on 30 May 2022



Glenn Honey
Managing Director