

UK Declaration of Conformity (UKCA Marking)

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
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Sleeves

RAD-AC-AS	Arm Sleeve
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The declaration of conformity with the provisions of the Personal Protective Equipment Regulations (Regulation 2016/425 as brought into UK law and amended) comply with the designated standards EN ISO 12345:2020 to meet the Manufacturer's Specifications; and the requirements of IEC 61331-1:2014 and IEC 61331-3:2014. These requirements are identical to the PPE which is the subject of the Type-Examination Certificate issued by BTTG, Notified Body 0338, Manchester M17 1EH (formerly CE Marking under certification number 523556/1).

The item is subject to the conformity assessment procedure conformity to type based on quality assurance of the production process (Module D) under surveillance of the Approved Body BTTG, 0338 (formerly CE Marking under certification number 54183).

Drapes

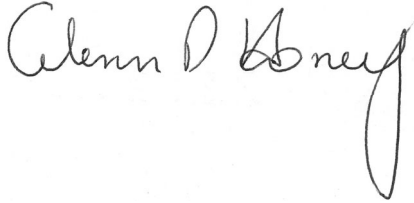
RAD-DP-MPD-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Multipurpose 300mm x 430mm
RAD-DP-MRF-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Multipurpose 300mm x 430mm with fenestration 90mm x 50mm
RAD-DP-MSF-250-NLB	RADdrape [®] Sterile Radiation Attenuation Drape - Multipurpose 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 Personal Protective Equipment Regulations (Regulation 2016/425 as brought into UK law and amended) comply with the designated standards EN ISO 12345:2020 to meet the Manufacturer's Specifications; and have the radiation protective qualities as defined by the requirements of IEC 61331-1:2014. This is the subject to the upcoming Type-Examination Certificate conducted by BTTG, Notified Body 0338, Manchester M17 1EH.

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 BTTG, 0338.

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



Glenn Honey
Managing Director