

EU Declaration of Conformity -Drapes

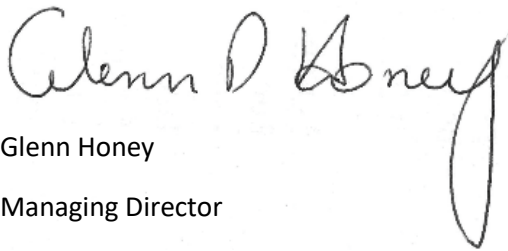
This EU declaration of conformity is issued under the sole responsibility of Imaging Solutions Pty Ltd who confirms that the products listed on pages two and meet the provision of the Regulation (EU) 2016/425 on personal protective equipment.

Imaging Solutions and its related entities are exclusively licensed to manufacture, market and distribute RADsafe® radiation protection products, associated accessories, consumables and related RAD brands.



The notified body *Shirley Technologies (Europe) Limited, Sky Business Centre, Port Tunnel Business Park, Office 13, Unit 21, Clonshaugh Business and Technology Park, Dublin 17, ROI*, Notified Body No. 2895, performed the conformity assessment and issued Module B EU type-examination certificate, Certificate No. SH00127. Product is subject to the scheduled periodic surveillance procedure set out in Module D under the supervision of the Notified Body.

Signed for and on behalf of Imaging Solutions on 9th May 2024.



Glenn Honey
Managing Director

Product Code	Product Name	Applied Standards
Sterile Radiation Protection Drapes		
RAD-DP-BSS-4330-NLB61-20	Biliary split shield 300mm x 430mm with slit	IEC 61331-1:2014
RAD-DP-FEA-4330-NLB61-20	Femoral Entry Angiopathy Drape 300mm X 430 with 40mm hole and slit	
RAD-DP-MCF-4330-NLB61-20	Multipurpose drapes 300mm x 430mm with scoop fenestration (centre) 90mm x 4.5mm	IEC 61331-1:2014
RAD-DP-MPD-4330-NLB61-20	Multipurpose Drape 300mm X 430mm	IEC 61331-1:2014
RAD-DP-MRF-4330-NLB61-20	Multipurpose Drape 300mm x 430mm with fenestration 90mm x 50mm	IEC 61331-1:2014
RAD-DP-MSF-4330-NLB61-20	Multipurpose drape 300mm x 430mm with scoop fenestration (side) 90mm x 4.5mm	IEC 61331-1:2014
RAD-DP-BSS-4330-NLH55-20	Biliary split shield 300mm x 430mm with slit	IEC 61331-1:2014
RAD-DP-FEA-4330-NLH55-20	Femoral Entry Angiopathy Drape 300mm X 430 with 40mm hole and slit	IEC 61331-1:2014
RAD-DP-MCF-4330-NLH55-20	Multipurpose drapes 300mm x 430mm with scoop fenestration (centre) 90mm x 4.5mm	IEC 61331-1:2014
RAD-DP-MPD-4330-NLH55-20	Multipurpose Drape 300mm X 430mm	IEC 61331-1:2014
RAD-DP-MRF-4330-NLH55-20	Multipurpose Drape 300mm x 430mm with fenestration 90mm x 50mm	IEC 61331-1:2014
RAD-DP-MSF-4330-NLH55-20	Multipurpose drape 300mm x 430mm with scoop fenestration (side) 90mm x 4.5mm	IEC 61331-1:2014
RAD-DP-BSS-4330-NLH55-10	Biliary split shield 300mm x 430mm with slit	IEC 61331-1:2014
RAD-DP-FEA-4330-NLH55-10	Femoral Entry Angiopathy Drape 300mm X 430 with 40mm hole and slit	IEC 61331-1:2014
RAD-DP-MCF-4330-NLH55-10	Multipurpose drapes 300mm x 430mm with scoop fenestration (centre) 90mm x 4.5mm	IEC 61331-1:2014
RAD-DP-MPD-4330-NLH55-10	Multipurpose Drape 300mm X 430mm	IEC 61331-1:2014
RAD-DP-MRF-4330-NLH55-10	Multipurpose Drape 300mm x 430mm with fenestration 90mm x 50mm	IEC 61331-1:2014
RAD-DP-MSF-4330-NLH55-10	Multipurpose drape 300mm x 430mm with scoop fenestration (side) 90mm x 4.5mm	IEC 61331-1:2014