

DECLARATION OF EC-CONFORMITY IN ACCORDANCE WITH (EU) 2016/425, ANNEX IV

Rego X-Ray GmbH
Stuttgarter Straße 5
D-86154 Augsburg Germany

Declares as solely responsible that the X-ray Protection Clothing PPE with Lightweight Lead Material described hereafter:

Coat Apron C+ with Velcro closure, Coat Apron C+ with Belt closure, Classic Line/Silver Line
Mantelschürze mit Klettverschluss, Mantelschürze mit Gürtelverschluss, Classic Line/Silver Line
Pb 0,25 mm front / Pb 0,25 mm at 50-150 kV for the back
Pb 0,35 mm front / Pb 0,25 mm at 50-150 kV for the back

Double Sided Apron, Classic Line/Silver Line
Doppelschürze, Classic Line/Silver Line
Pb 0,25 mm at 50-150 kV for front/back
Pb 0,35 mm front / Pb 0,25 mm at 50-150 kV for the back

Wrap Around Apron partially overlapping, Classic Line/Silver Line
Rundumschürze teilweise überlappend, Classic Line/Silver Line
Pb 0,25 mm at 50-150 kV for front/back
Pb 0,35 mm front / Pb 0,25 mm at 50-150 kV for the back

Wrap Around Apron fully overlapping, Classic Line/Silver Line
Rundumschürze komplett überlappend, Classic Line/Silver Line
Pb 0,25 mm at 50-150 kV for front/back
Pb 0,35 mm front / Pb 0,25 mm at 50-150 kV for the back

Skirt & Vest (set which must be worn together as an ensemble) partially overlapping, Classic Line/Silver Line
Weste & Rock teilweise überlappend, Classic Line/Silver Line
Pb 0,25 mm at 50-150 kV for front/back
Pb 0,35 mm front / Pb 0,25 mm back at 50-150 kV

Skirt & Vest fully overlapping (set which must be worn together as an ensemble), Classic Line/Silver Line
Weste & Rock komplett überlappend, Classic Line/Silver Line
Pb 0,25 mm at 50-150 kV for front/back
Pb 0,35 mm front / Pb 0,25 mm back at 50-150 kV

Surgical Apron with Velcro closures, Classic Line/Silver Line
Chirurgenschürze mit Klettverschluss, Classic Line/Silver Line
Pb 0,25 mm at 50-150 kV front/shoulders
Pb 0,35 mm front at 50-150 kV

Dental Apron – Standard Patient Protection, Classic Line/Silver Line
Dentalschürze – Standard Patientenschutz, Classic Line/Silver Line
Pb 0,35 mm front at 50-150 kV

Dental Apron – Panoramic Patient +Backside Protection, Classic Line/Silver Line
Dentalschürze – Panorama Patientenschutz mit Rückenschutz, Classic Line/Silver Line
Pb 0,35 mm front at 50-150 kV

Dental Apron – Operator + Patient Protection, Classic Line/Silver Line
Dentalschürze – Anwender-/ Patientenschutz, Classic Line/Silver Line
Pb 0,35 mm front at 50-150 kV

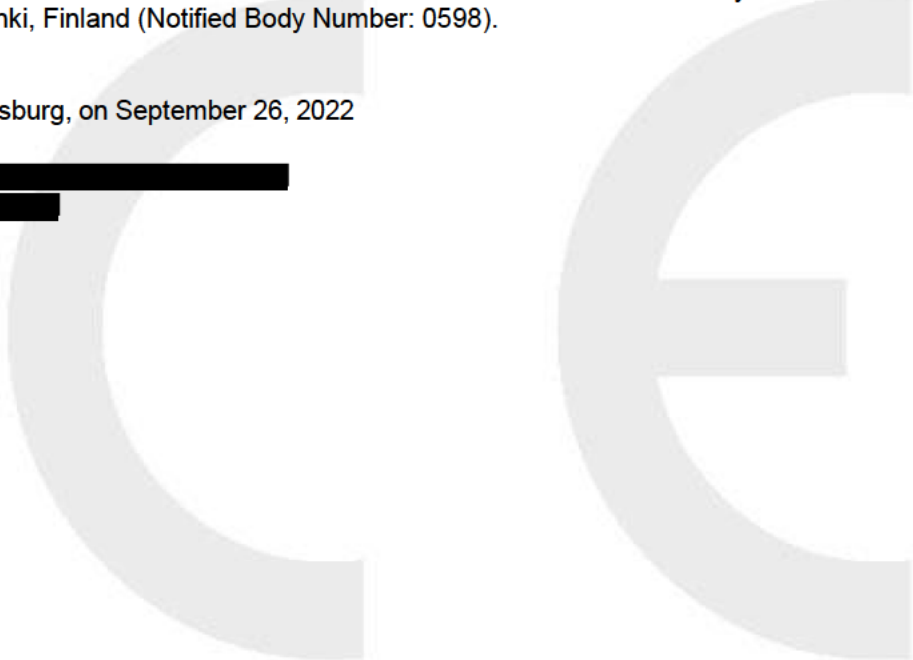
Complies with the requirements of regulation (EU) 2016/425 (Class III) and the harmonized standards of EN 61331-3:2014 and EN 61331-1:2014 which had previously deemed to meet the basic health and safety requirements (Annex II) of the regulation. This declaration of conformity is issued under the solely responsibility of the manufacturer.

The notified body, SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland (Notified Body Number: 0598) performed the EU type-examination (Module B) and issued the EU type-examination certificate No. 0598/PPE/22/3897.

And the PPE is subject to conformity to type based on quality assurance of the production process with Module D certificate No. F118/962438 under surveillance of the notified body SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland (Notified Body Number: 0598).

Done at Augsburg, on September 26, 2022

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Declares as solely responsible that the X-ray Protection Clothing PPE with Lightweight Lead Material described hereafter:

Coat Apron C+ with Velcro closure, Coat Apron C+ with Belt closure, Classic Line/Silver Line
Mantelschürze mit Klettverschluss, Mantelschürze mit Gürtelverschluss, Classic Line/Silver Line
Pb 0,50 mm front / Pb 0,25 mm at 50-150 kV for the back

Coat Apron for Children, Classic Line/Silver Line
Mantelschürze für Kinder, Classic Line/Silver Line
Pb 0,50 mm front / Pb 0,25 mm at 50-150 kV for the back

Double Sided Apron, Classic Line/Silver Line
Doppelschürze, Classic Line/Silver Line
Pb 0,50 mm front / Pb 0,25 mm at 50-150 kV for the back

Wrap Around Apron partially overlapping, Classic Line/Silver Line
Rundumschürze teilweise überlappend, Classic Line/Silver Line
Pb 0,50 mm front / Pb 0,25 mm at 50-150 kV for the back

Wrap Around Apron fully overlapping, Classic Line/Silver Line
Rundumschürze komplett überlappend, Classic Line/Silver Line
Pb 0,50 mm front / Pb 0,25 mm at 50-150 kV for the back

Wrap Around Apron for children, Classic Line/Silver Line
Rundumschürze für Kinder, Classic Line/Silver Line
Pb 0,50 mm front / Pb 0,25 mm at 50-150 kV for the back

Skirt & Vest (set which must be worn together as an ensemble) partially overlapping, Classic Line/Silver Line
Weste & Rock teilweise überlappend, Classic Line/Silver Line
Pb 0,50 mm front / Pb 0,25 mm back at 50-150 kV

Skirt & Vest fully overlapping (set which must be worn together as an ensemble), Classic Line/Silver Line
Weste & Rock komplett überlappend, Classic Line/Silver Line
Pb 0,50 mm front / Pb 0,25 mm back at 50-150 kV

Surgical Apron with Velcro closures, Classic Line/Silver Line
Chirurgenschürze mit Klettverschluss, Classic Line/Silver Line
Pb 0,50 mm front at 50-150 kV

Dental Apron – Standard Patient Protection, Classic Line/Silver Line
Dentalschürze – Standard Patientenschutz, Classic Line/Silver Line
Pb 0,50 mm front at 50-150 kV

Dental Apron – Panoramic Patient +Backside Protection, Classic Line/Silver Line
Dentalschürze – Panorama Patientenschutz mit Rückenschutz, Classic Line/Silver Line
Pb 0,50 mm front at 50-150 kV

Dental Apron – Operator + Patient Protection, Classic Line/Silver Line
Dentalschürze – Anwender-/ Patientenschutz, Classic Line/Silver Line
Pb 0,50 mm front at 50-150 kV

Complies with the requirements of regulation (EU) 2016/425 (Class III) and the harmonized standards of EN 61331-3:2014 and EN 61331-1:2014 which had previously deemed to meet the basic health and safety requirements (Annex II) of the regulation. This declaration of conformity is issued under the solely responsibility of the manufacturer.

The notified body, SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland (Notified Body Number: 0598) performed the EU type-examination (Module B) and issued the EU type-examination certificate No. 0598/PPE/22/3897.

And the PPE is subject to conformity to type based on quality assurance of the production process with Module D certificate No. FI18/962438 under surveillance of the notified body SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland (Notified Body Number: 0598).

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Declares as solely responsible that the X-ray Protection Clothing PPE with Lightweight Lead Material described hereafter:

Half Apron with Velcro closure belt/ hip clamp grip, Classic Line/Silver Line
Halbschürze mit Klettverschluss/Hüftspannbügel, Classic Line/Silver Line
Pb 0,5 mm at 50-150 kV

Ovary Shields, Classic Line/Silver Line
Ovarienschutz, Classic Line/Silver Line
Pb 1,0 mm at 50-150 kV

Ovary Shields for infants – Daphne, Silver Line
Ovarienschutz für Säuglinge und Kleinkinder – Daphne, Silver Line
Pb 1,0 mm at 50-150 kV

Gonad Shields, Classic Line/Silver Line
Gonadenschutz, Classic Line/Silver Line
Pb 1,0 mm at 50-150 kV

Gonad Shields for infants – Apollo, Silver Line
Gonadenschutz für Säuglinge und Kleinkinder – Apollo, Silver Line
Pb 1,0 mm at 50-150 kV

Complies with the requirements of regulation (EU) 2016/425 (Class III) and the harmonized standards of EN 61331-3:2014 and EN 61331-1:2014 which had previously deemed to meet the basic health and safety requirements (Annex II) of the regulation. This declaration of conformity is issued under the solely responsibility of the manufacturer.

The notified body, SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland (Notified Body Number: 0598) performed the EU type-examination (Module B) and issued the EU type-examination certificate No. 0598/PPE/22/3897.

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Declares as solely responsible that the X-ray Protection Clothing PPE with Lightweight Lead Material described hereafter:

Standard Thyroid Collar, Classic Line/Silver Line
Schilddrüsenschutz standard, Classic Line/Silver Line
Pb 0,50 mm at 50-150 kV

Sternum Thyroid Collar, Classic Line/Silver Line
Sternumschutz für Schilddrüse, Classic Line/Silver Line
Pb 0,50 mm at 50-150 kV

Panoramic Thyroid Collar, Classic Line/Silver Line
Panorama Schilddrüsenschutz, Classic Line/Silver Line
Pb 0,50 mm at 50-150 kV

Protection Cap, Classic Line/Silver Line
Strahlenschutzkappe, Classic Line/Silver Line
Pb 0,50 mm at 50-150 kV

Shin Protection flexible, Classic Line/Silver Line
Schienbeinschutz flexible, Classic Line/Silver Line
Pb 0,50 mm at 50-150 kV

Complies with the requirements of regulation (EU) 2016/425 (Class III) and the harmonized standards of EN 61331-3:2014 and EN 61331-1:2014 which had previously deemed to meet the basic health and safety requirements (Annex II) of the regulation. This declaration of conformity is issued under the sole responsibility of the manufacturer.

The notified body, SGS United Kingdom Ltd Systems & Services Certification 202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK performed the EU type-examination (Module B) and issued the EU type-examination certificate No. 0598/PPE/22/3897.

And the PPE is subject to conformity to type based on quality assurance of the production process with Module D certificate No. F118/962438 under surveillance of the notified body SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland (Notified Body Number: 0598).

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