

**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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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

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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).

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:

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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