

Certificate FI19/964255

Surg Equip Ltd (T/A Amray Medical)

Unit 9, Greenhills Industrial Village,
Drogheda,
Co Louth.
Republic of Ireland.

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 23 October 2019 until 23 October 2024
2. Certified since 23 October 2019

Authorised by

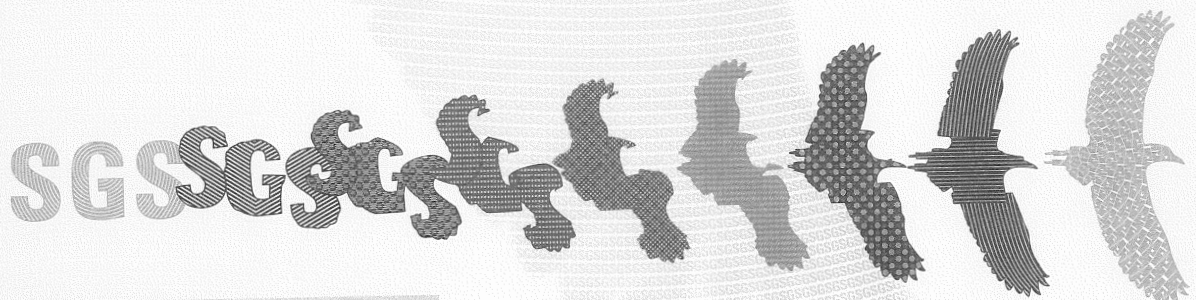
FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

SGS FIMKO OY, Notified Body 0598

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**Surg Equip Ltd
(T/A Amray Medical)**

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 2

PPE Product

AmRay "Light Lead" X-ray protective clothing providing protection to parts of the body which are available with uniform nominal attenuation equivalences of 0.25mm, 0.35mm and 0.5mm Pb at 60-150kV in each panel. This clothing is available in the range of styles described in Annex 1.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:
manufacturer's technical specification (based on EN 61331-3:2014(Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing and protective devices for gonads.) and on testing to EN 61331-1:2014 plus latest guidance notes)

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference: Technical file No 1 Rev 1.

SGS Reference Number UK/CRS 239834

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request.

Surg Equip Ltd (T/A Amray Medical)

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 2

Annex 1

Semi-Wrap apron (Model 01)

Single Front Apron Models A,B,C and Classic (Models 07 & 09);

Theatre Drop Off Apron (Model 08);

Double Sided Apron (Model 05);

Vest & Skirt (Models 31,44,45,46,47,48,49, 04 & 04NM);

Coat Apron (Model 06);

Backsaver (Model 02);

Maternity Apron (Model 12);

Urology Apron (Model 13)

The following models are available in 0.35mm, 0.5mm and 1.0mm Pb only;

Orthopantomogram (Model 11);

Dental (Model 10);

Accessories;

Thyroid Collar (A, B-8cm & B-12cm), C, Cosy Collar;

The following models are available in 0.25mm, 0.35mm, 0.5mm and 1.0mm Pb only;

Accessories;

Backshield, Hand Protector, Epaulette, Shin Protector, Arm Protector,

Foot Protector, Lead cap;

The following models are available in 0.5mm and 1.0mm Pb only:

Accessories;

Gonad Protector, Breast Protector;

The following model is available in 1.0mm Pb only:

Ovarian Shield.

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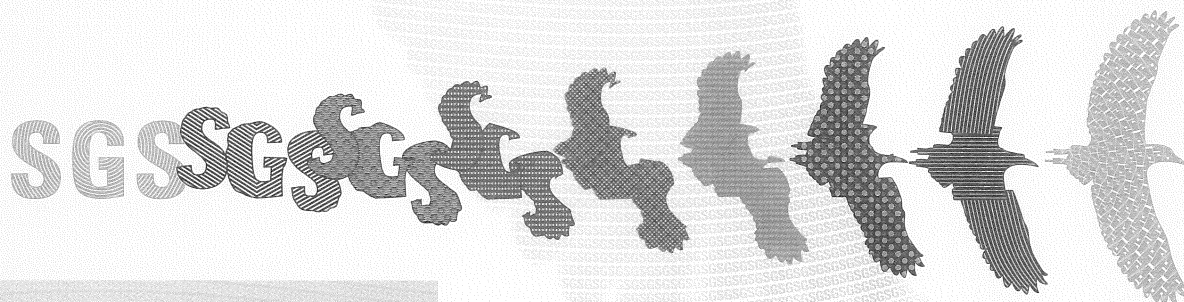


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Surg Equip Ltd (T/A Amray Medical)

Regulation (EU) 2016/425 Module B, EU type-examination

Issue 2

PPE Product

AmRay "Light Plus" X-ray protective clothing providing protection to parts of the body which are available with uniform nominal attenuation equivalences of 0.25mm, 0.35mm and 0.5mm Pb at 60-110kV in each panel. This clothing is available in the range of styles described in Annex 1.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

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Surg Equip Ltd (T/A Amray Medical)

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 2

Annex 1

Semi-Wrap apron (Model 01)
Single Front Apron Models A,B,C and Classic (Models 07 & 09);
Theatre Drop Off Apron (Model 08);
Double Sided Apron (Model 05);
Vest & Skirt (Models 31,44,45,46,47,48,49, 04 & 04NM);
Coat Apron (Model 06);
Backsaver (Model 02);
Maternity Apron (Model 12);
Urology Apron (Model 13)

The following models are available in 0.35mm, 0.5mm and 1.0mm Pb only;

Orthopantomogram (Model 11);
Dental (Model 10);
Accessories;

Thyroid Collar (A, B-8cm & B-12cm), C, Cosy Collar;

The following models are available in 0.25mm, 0.35mm, 0.5mm and 1.0mm Pb only:

Accessories;

Backshield, Hand Protector, Epaulette, Shin Protector, Arm Protector,
Foot Protector, Lead cap;

The following models are available in 0.5mm and 1.0mm Pb only:

Accessories;

Gonad Protector, Breast Protector;

The following model is available in 1.0mm Pb only:

Ovarian Shield.

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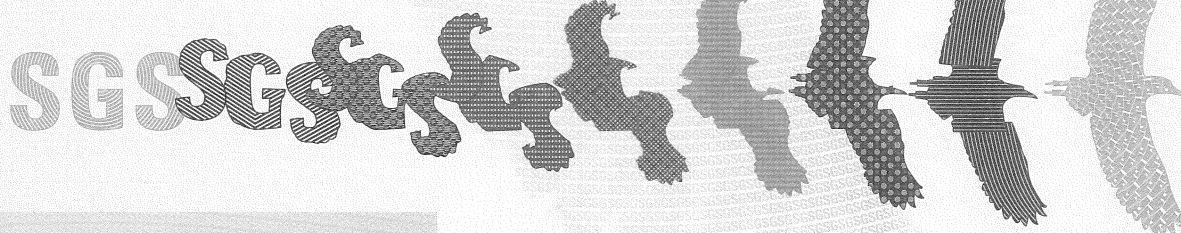


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Surg Equip Ltd (T/A Amray Medical)

Regulation (EU) 2016/425 Module B, EU type-examination

Issue 2

PPE Product

AmRay "Supreme Lead Free" X-ray protective clothing providing protection to parts of the body which are available with uniform nominal attenuation equivalences of 0.25mm, 0.35mm and 0.5mm Pb at 60-110kV in each panel.

This clothing is available in the range of styles described in Annex 1.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

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Single Front Apron Models A,B,C and Classic (Models 07 & 09);
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Double Sided Apron (Model 05);
Vest & Skirt (Models 31,44,45,46,47,48,49, 04 & 04NM);
Coat Apron (Model 06);
Backsaver (Model 02);
Maternity Apron (Model 12);
Urology Apron (Model 13)

The following models are available in 0.35mm, 0.5mm and 1.0mm Pb only;

Orthopantomogram (Model 11);

Dental (Model 10);

Accessories;

Thyroid Collar (A, B-8cm & B-12cm), C, Cosy Collar;

The following models are available in 0.25mm, 0.35mm, 0.5mm and 1.0mm Pb only:

Accessories;

Backshield, Hand Protector, Epaulette, Shin Protector, Arm Protector,

Foot Protector, Lead cap;

The following models are available in 0.5mm and 1.0mm Pb only:

Accessories;

Gonad Protector, Breast Protector;

The following model is available in 1.0mm Pb only:

Ovarian Shield.