

OLEY TIBBI URUNLER VE MEDIKAL MALZEMELER SANAYI TICARET LIMITED SIRKETI

PARSELLER MAHALLESİ MENEKSE CADDESİ FEYYAZ SOKAK
NO : 2 UMRANIYE – ISTANBUL- TURKEY

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 11 September 2019 until 11 September 2024
Issue 1. Certified since 11 September 2019

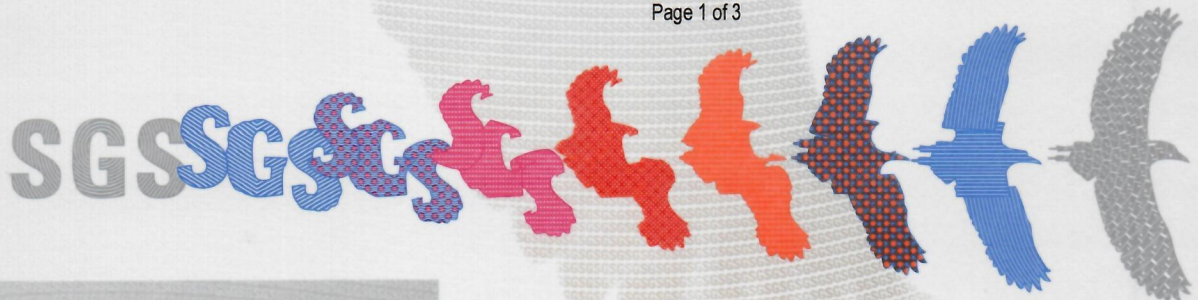


Authorised by

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**OLEY TIBBI URUNLER VE
MEDIKAL MALZEMELER
SANAYI TICARET LIMITED
SIRKETI**

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

"ixxir" Lead X-ray protective clothing providing protection to parts of the body which are available with uniform nominal attenuation equivalences ranging from 0.25mm to 0.50mm Pb in each panel. This clothing is available in a range of styles & sizes specified 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 specification¹ (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 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: Documentation number 2311, revision 2 dated 10/05/2019

SGS Reference Number UK/CRS 238904.

¹ The validity of this certificate may have to be reviewed in the light of new or amended harmonised standards

This certificate remains the property of SGS United Kingdom Ltd to whom it must be returned on request.



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Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

Annex 1

Front Apron, which are available in seven nominal sizes and with nominal attenuation equivalences of 0.25, 0.35 or 50mm Pb at 60-150kV, Article codes 1100-1225;

Double Sided Apron, which are available in seven nominal sizes and with nominal attenuation equivalences of 0.25, 0.35 or 50mm Pb at 60-150kV, Article codes 2100-2225;

Vest and Skirt Apron, which are available in seven nominal sizes and with nominal attenuation equivalences of 0.25, 0.35 or 50mm Pb at 60-150kV, Article codes 4100-4225;

Dental Apron, which are available in four nominal sizes and with nominal attenuation equivalences of 0.35 or 50mm Pb at 60-150kV, Article codes 3200-3207;

Panoramic Apron, which are available in six nominal sizes and with nominal attenuation equivalences of 0.25, 0.35 or 50mm Pb at 60-150kV, Article codes 3208-3225;

Children Apron, which are available in three nominal sizes and with nominal attenuation equivalences of 0.25, 0.35 or 50mm Pb at 60-150kV, Article codes 3300-3308;

Patient Apron, which are available in five nominal sizes and with nominal attenuation equivalences of 0.25, 0.35 or 50mm Pb at 60-150kV, Article codes 1500-1514;

Radiation Glove, which are available in three nominal sizes and with nominal attenuation equivalences of 0.25, 0.35 or 50mm Pb at 60-150kV, Article codes 6000-6008;

Thyroid Collar, which are available in six nominal sizes and with nominal attenuation equivalences of 0.35 or 50mm Pb at 60-150kV, Article codes 5100-5111;

Gonad Protective. which are available in four nominal sizes and with nominal attenuation equivalences 50mm Pb at 60-150kV, Article codes 5700-5703.

