

OLEY TIBBI URUNLER VE MEDIKAL MALZEMELER SANAYI TICARET LIMITED SIRKETI

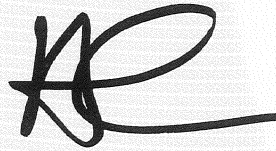
PARSELLER MAHALLESİ MENEKSE CADDESİ FEYYAZ SOKAK
NO : 2 UMRANIYE – ISTANBUL- TURKEY

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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MEDIKAL MALZEMELER SANAYI
TICARET LIMITED SIRKETI**

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1
PPE Product

"ixxir" Lead-Free 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.



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