

Oley Tıbbi Ürünle ve Medikal Mlz. San. Tic. Ltd. Şti

Parseller Mah. Menekşe Cad.

Feyyaz Sok. No:2-2/1-2/2-2/4 Ümraniye

İstanbul-Turkey.

23.12.2020

Transfer of certification from SGS United Kingdom Ltd (NB 0120) to SGS Fimko Oy (NB 0598)

Following your request, I confirm that the Article 10/Module B certificates listed in Annex A to this letter have been formally transferred to SGS Fimko Oy, Helsinki, who will act as the European Notified Body. The Notified Body Number for SGS Fimko Oy, listed on the European Commission's NANDO database is 0598.

The Certificate Number has not changed, and retains the prefix associated with SGS United Kingdom Ltd. who originally issued the documents.

Although we cannot mandate any specific text for you to use in your Declaration of Conformity, we suggest that when listing the certificate number in the declaration, you indicate both the old UK and the new EU-27 Notified Body's details / Identification numbers.

Yours sincerely



K R Shepherd
(CRS) PPE Product Manager, SGS United Kingdom Ltd
Authorised signatory on behalf of SGS Fimko Oy

Annex A

Article 10 certificate numbers	Module B certificate numbers	Product Description/Code
	GB19/963928	SGS Reference Number UK/CRS 23890.- 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. Certification is based on technical file reference: Documentation number 2311, revision 2 dated 10/05/2019 SGS Reference Number UK/CRS 238904. 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 11001-12251; 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 21001-22251; 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 41001-42251; 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 32001-32071; 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 32081-32251; 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 33001-33081; 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 15001-15141; 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 60001-60081 ; 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 51 001-51111 ; Gonad Protective. which are available in four nominal sizes and with nominal attenuation equivalences 50mm Pb at 60-150kV, Article codes 57001-57031.
--	---