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...Protects Today and Future

EC DECLARATION OF CONFORMITY

Manufacturer:

OLEY TIBBI URUNLER

VE MEDİKAL MLZ.SAN.TIC.LTD.ŞTİ.

Parseller Mh. Menekse Cd. Feyyaz Sk. No:2/3 Umraniye Istanbul 34773 TURKEY

Declares that the new Personal Protective Equipment described after this:

Product Name: Radiation Protective Products

Models: Front Apron, Double Sided Apron, Vest and Skirt Apron, Dental Apron, Panaromic Apron, Children Apron, Patient Apron, Radiation Protective Curtain, Radiation Glove, Head Protective Cap,Lead Acrylic Half Face Shield,Thyroid Collar, Gonad Protective.

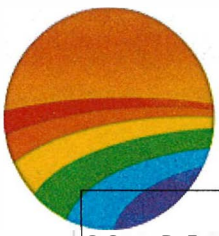
PRODUCT DESCRIPTION	LEAD PROTECTIVE		LEAD FREE PROTECTIVE	
	PRODUCTS SIZE	PROTECTIVE VALUE	PRODUCTS SIZE	PROTECTIVE VALUE
FRONT APRON	XSMALL - SMALL - MEDIUM - LARGE- XLARGE- XXLARGE- 3LARGE ARTICLE CODE FROM 1100 UNTIL 1225	0,25 MM PB - 0,35 MM PB - 0,50 MM PB	XSMALL - SMALL - MEDIUM - LARGE- XLARGE- XXLARGE- 3LARGE ARTICLE CODE FROM 11001 UNTIL 12251	0,25 MM LE - 0,35 MM LE - 0,50 MM LE
DOUBLE SIDED APRON	XSMALL - SMALL - MEDIUM - LARGE- XLARGE- XXLARGE- 3LARGE ARTICLE CODE FROM 2100 UNTIL 2225	0,25 MM PB - 0,35 MM PB - 0,50 MM PB	XSMALL - SMALL - MEDIUM - LARGE- XLARGE- XXLARGE- 3LARGE ARTICLE CODE FROM 21001 UNTIL 22251	0,25 MM LE - 0,35 MM LE - 0,50 MM LE
VEST SKIRT APRON	XSMALL - SMALL - MEDIUM - LARGE- XLARGE- XXLARGE- 3LARGE ARTICLE CODE FROM 4100 UNTIL 4183	0,25 MM PB - 0,35 MM PB - 0,50 MM PB	XSMALL - SMALL - MEDIUM - LARGE- XLARGE- XXLARGE- 3LARGE ARTICLE CODE FROM 41001 UNTIL 41831	0,25 MM LE - 0,35 MM LE - 0,50 MM LE
DENTAL APRON	ADULTS1 DA 1 ADULTS2 DA 2 CHILDREN1 DC 1 CHILDREN 2 DC 2 ARTICLE CODE	0,35 MM PB - 0,50 MM PB	ADULTS1 DA 1 ADULTS2 DA 2 CHILDREN1 DC 1 CHILDREN 2 DC 2 ARTICLE CODE	0,35 MM LE - 0,50 MM LE

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	FROM 3200 UNTIL 3207		FROM 3200 UNTIL 3207	
PANAROMIC APRON	ADULTS SMALL ADULTS MEDIUM ADULTS LARGE CHILDREN SMALL CHILDREN MEDIUM CHILDREN LARGE ARTICLE CODE FROM 3208 UNTIL 3225	0,25 MM PB - 0,35 MM PB - 0,50MM PB	ADULTS SMALL ADULTS MEDIUM ADULTS LARGE CHILDREN SMALL CHILDREN MEDIUM CHILDREN LARGE ARTICLE CODE FROM 32081 UNTIL 32251	0,25 MM LE - 0,35 MM LE - 0,50MM LE
CHILDREN APRON	SMALL MEDIUM LARGE ARTICLE CODE FROM 3300 UNTIL 3308	0,25 MM PB - 0,35 MM PB - 0,50MM PB	SMALL MEDIUM LARGE ARTICLE CODE FROM 33001 UNTIL 33081	0,25 MM LE - 0,35 MM LE - 0,50MM LE
PATIENT APRON	CHILDREN SMALL MEDIUM LARGE XLARGE ARTICLE CODE FROM 1500 UNTIL 1514	0,25 MM PB - 0,35 MM PB - 0,50MM PB	CHILDREN SMALL MEDIUM LARGE XLARGE ARTICLE CODE FROM 15001 UNTIL 15141	0,25 MM LE - 0,35 MM LE - 0,50 MM LE
RADIATION PROTECTIVE CURTAIN	SMALL MEDIUM LARGE XLARGE ARTICLE CODE FROM 8000 UNTIL 8011	0,25 MM PB - 0,35 MM PB - 0,50MM PB	SMALL MEDIUM LARGE XLARGE ARTICLE CODE FROM 80001 UNTIL 80111	0,25 MM LE - 0,35 MM LE - 0,50MM LE
RADIATION GLOVES	SMALL MEDIUM LARGE ARTICLE CODE FROM 6000 UNTIL 6008	0,25 MM PB - 0,35 MM PB - 0,50MM PB	SMALL MEDIUM LARGE ARTICLE CODE FROM 60001 UNTIL 60081	0,25 MM LE - 0,35 MM LE - 0,50MM LE
THYROID COLLAR	CHILDREN STANDART SUPPERED PANAROMIC CHILDREN PANAROMIC ADULTS CAPE ARTICLE CODE FROM 5100 UNTIL 5111	0,35 MM PB - 0,50 MMPB	CHILDREN STANDART SUPPERED PANAROMIC CHILDREN PANAROMIC ADULTS CAPE ARTICLE CODE FROM 51001 UNTIL 51111	0,35 MM LE - 0,50MM LE



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GONAD PROTECTIVE	ADULTS1 ADULTS2 CHILDREN1 CHILDREN 2 ARTICLE CODE FROM 5700 UNTIL 5703	0,50 MM PB	ADULTS1 ADULTS2 CHILDREN1 CHILDREN 2 ARTICLE CODE FROM 57001 UNTIL 57031	0,50 MM LE
HEAD PROTECTIVE CAP	STANDARD SIZE ARTICLE CODE FROM HC050 UNTIL HC025	0,25MM PB 0,35MM PB 0,50 MM PB	STANDARD SIZE ARTICLE CODE FROM HC0501 UNTIL HC0251	0,25MM LE 0,35MM LE 0,50 MM LE
LEAD ACRYLIC HALF FACE SHIELD	STANDARD SIZE ARTICLE CODE HFS100	125MM PB	STANDARD SIZE ARTICLE CODE	

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The products described herein are classified as Personal Protective Equipment (PPE) in accordance with Regulation (EU) 2016/425. They are not classified as Medical Devices within the meaning of Regulation (EU) 2017/745 or any other applicable medical device legislation.

This products are not medical not ivd

Oley Tibbi Urunler is in conformity with the provision of **Regulation EU 2016/425** and, where such is the case, with the national Standard transposing **harmonized Standard no EN 61331-3:2014, EN 61331-1:2014**

is identical to PPE which is the subject of EC-Type Examination Certificates issued by MNA, Küçükbakkalköy Mah. Yenidoğan Cad. No:21Ataşehir/İstanbul, **Notified Body Number: 2841**

is subject to the procedure set out in **Module C2 of the Directive Regulation EU 2016/425** under the supervision of the notified body MNA, Küçükbakkalköy Mah. Yenidoğan Cad. No:21Ataşehir/İstanbul, **Notified Body Number: 2841**

A Quality Management System based on

ISO 9001:2015 (Certificate QMS-006442. Date Certificate Expires 05.03.2027)
has been implemented towards production and quality assurance.

Yakup SENTURK - General Manager and Head of Quality

DepartmentOLEY Tibbi Urunler Ve Medical Mlz .San.Tic.Ltd.Sti

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