Notified Body Number: 2841

AB Tip İnceleme Sertifikası
EU Type-Examination Certificate

Belge No / ***Certificate No*** : 36-20-02-R03
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 05.01.2021-01.09.2025
Belge Geçerlilik Tarihi / ***Document Validity Period*** : 5 yıl / *5 years*
Firma Unvanı ve Adresi /
Company Name and Address : ORJİN Sağlık Ürünleri Medikal Tekstil Turizm İnşaat San. Ve Tic. Ltd. Şti.
6118 Sokak No: 9 Egemenlik Mah. Bornova/ İZMİR

Ürün Adı /Modeller / ***Product Name / Models*** : ORJİN 1131
Direktifi / ***Directive*** : 2016/425 REGULATION
Modülü/Kategori / ***Module / Category*** : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Test Rapor No/ları / ***Test Report No*** : MNA M-2020-00250
Ürün Tipi / ***Product Type:***

- EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar - Parçacıklara karşı koruma amaçlı filtreli yarım maskeler/ *Respiratory protective devices - Filtering half masks to protect against particles*

Ürünün Malzeme Bilgisi / ***Product Material Information*****:** ORJİN 1131 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ *ORJİN 1131 model products are manufactured using fabric, elastic strap, nose clip, filter layer.*
Revizyon nedeni/ ***Reason for revision:*** Model adı revize edilmiştir./ *The model name has been revised.*

Volkan AKIN	***Okan AKEL***
05.01.2021	***05.01.2021***
Karar Verici / Approver	***Şirket Müdürü / General manager***

Notified Body Number: 2841

ATTACHMENTS (36-20-02-R03)

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

Model : ORJİN 1131

yyyy/mm

Or Condition of Storage

MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

ORJIN

SCHUTZMASKE

[redacted]

BA[illegible]N & VIREN & PARTIKELN

EN:149:2001 - A1:20[illegible]

Príloha č. 2 - Návrh na plnenie kritérií

Identifikačné údaje:

Názov zákazky: „Výzva č. 2 - Respirátor FFP2 bez výdychového ventilu“

Uchádzač: ..... B2B SERVICES a.s. .....

Adresa sídla: ..... NOVÉ ZÁHRADY I 13/A, BRATISLAVA .....

IČO: ..... 36726893 .....

Číslo účtu (IBAN): .....[redacted]

Telefónne číslo: .....[redacted]

E-mailová adresa: .....[redacted]@B2B-SERVICES.SK

Ponuková cena v súlade s opisom predmetu zákazky:

Názov	**Celková cena** v eur s DPH
Respirátor FFP2 bez výdychového ventilu **v celkovom množstve 120 000 ks**	**18 000,-**

Cena uvedená uchádzačom obsahuje všetky náklady, ktoré uchádzačovi vzniknú v súvislosti s plnením predmetnej zákazky. Verejný obstarávateľ upozorňuje, že novelou 67/2020 Z. z. účinnou od 12.02.2021 sa na respirátory FFP3 a FFP2 zaviedla 0 (nulová) DPH. Na základe uvedeného **bude celková cena s DPH totožná s celkovou cenou bez DPH a to bez ohľadu na to, či uchádzač je alebo nie platiteľom DPH.**

Čestné vyhlásenie: Predložením tejto ponuky zároveň **čestne vyhlasujem**, že postupujem v súlade s **etickým kódexom** uchádzača vydaným Úradom pre verejné obstarávanie:

https://www.uvo.gov.sk/zaujemcauchadzac/eticky-kodex-zaujemcu-uchadzaca-54b.html

V BRATISLAVE dňa 25.5.2021

[redacted]

pečiatka a podpis osoby oprávnenej konať za uchádzača

EU DECLARATION OF CONFORMITY

MANUFACTURER

ORJIN SAGLIK URUNLERI MEDIKAL TEKSTIL TURIZM INSAAT SANAYI VE TICARET LIMITED SIRKETI
EGEMENLIK MAH. 6155. SOK. NO 3 A BORNOVA IZMIR TURKIYE

This declaration of comformity is drawn up under the manufacturer's own authority and responsibility.

PRODUCT DESCRIPTION
Brand Name: ORJİN Modeli 1232
Filtering half mask
Classification: FFP2, FFP3, CHILD FFP2

Particle Filtering hallf Face Mask in Category ill product according to (FM 2016/425 Personal Protective Equipment Regulation

The manufacturer declares on his sole responsibility that the product above is, under conditions of Normal use and conditions defined by the manufacturer safe and meets all the necessary legal Condutions and requirements. The product is a personal protective equipment that is intended for single Use and solely in accordance with the Manufacturer's instructions.

The Conformity is ensured with the following mechanism:

Complies with EU 2016/425 Personal Protective Equipment Regulation establishing technical requirements for Category III products.
Complies with Essential Health and Safety Requirements of Techinal harmonized Standard EN 149:2001 +A 1:2009
All required tests referred in above standards arc conducted.
Complies with other relevant harmonized legislation and community standards.
For the assessment of conformity the EU Type Examination certificates (Serial No: 2841 36-20-01-R3) is issued after all technical evaluations for conformity to the regulation and harmonized standards contucted, by;
The notified body MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ. Küçükbakkalköy Mah. Yenidoğan Cad. No:21 Ataşehir/İstanbul, as Notified Body number 2841
The products is under surveillance of same Notified Body, NB 2841 according to the Annex (Module C2 36-20-01-R03-01) of the PPE Regulation (EU) 2016/425, for quality assurance,

MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment regulation and the harmonized product standards given above.

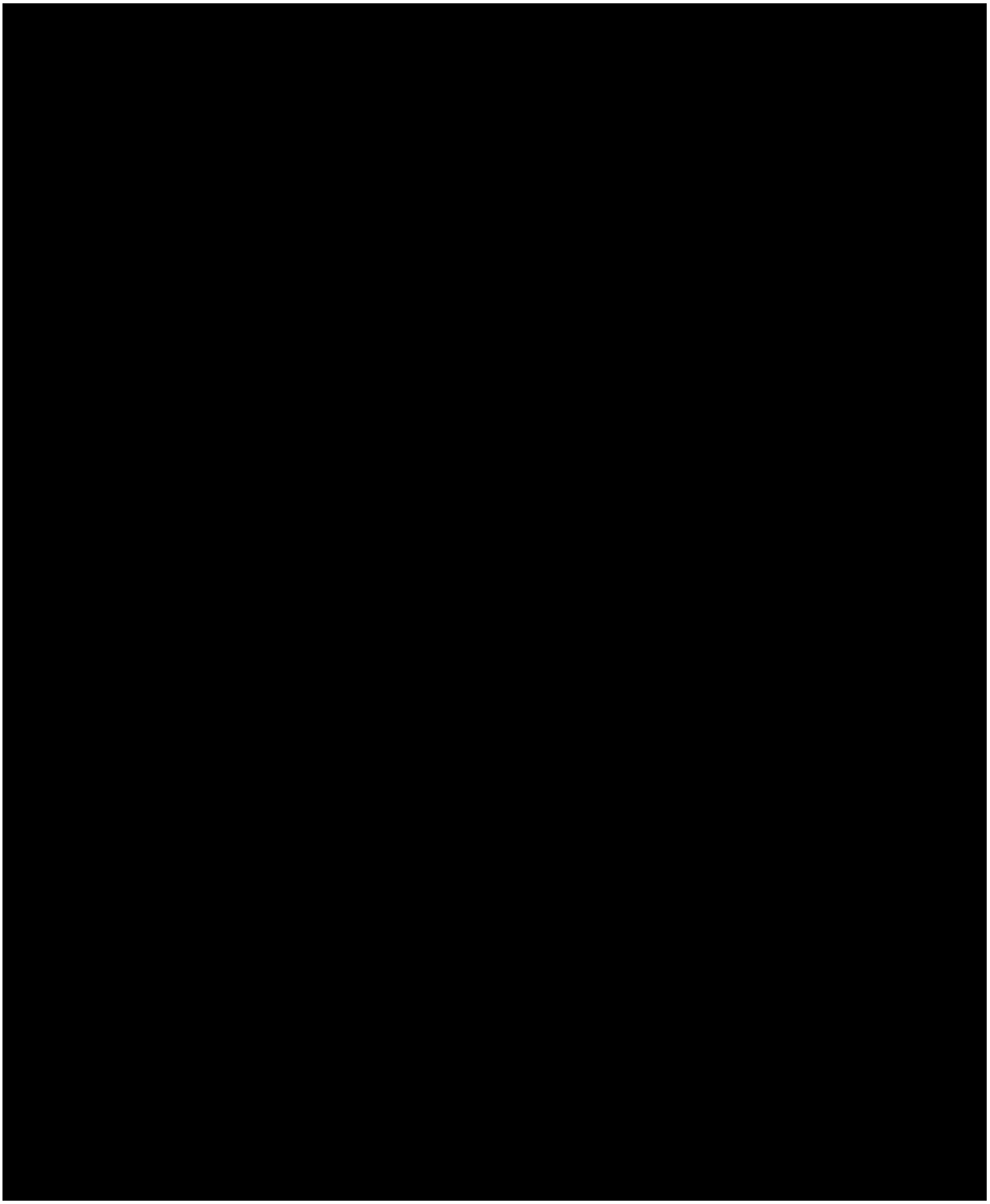
MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documention and technical requirements for this type of products.

BORA ÖNGÖÇMEN
Chief Executive Officer
15.12.2020 İzmir

[redacted]

CE
2841



Výrobca/Výrobce
Changzhou Huankang Medical Device Co., Ltd.
Adresa/Cím: No.22, Changhe Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu, Ch
web: www.huankang.com

Notifikovaná osoba/ Notifikovaná osoba
CCQS Certification Services Limited
Adresa/Cím: Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland (NB 2834)

LOT NO.
EXPIRATION

EAN CODE