

CE ATTESTATION OF CONFORMITY

Related Directives:

MEDICAL DEVICES 93/42/EEC----TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Class / Sinif: CLASS 1 / SINIF 1, NON STERILE

Description of Product:

MEDICAL MASK TIBBİ MASKE

Color:

WHITE / BEYAZ

BLUE / MAVİ

Trade Mark: **SMART**

Regulations Applied acc. To Harmonized Standards: TS EN 62366-1:2016, TS EN ISO 15223-1:2012, TS EN ISO 14971:2012, TS EN ISO 13485:2016

Manufactured by

ALİYA GİYİM TEKS<mark>TİL SAN</mark>AYİ VE TİCARET ANONİM ŞİRKETİ ISLAHİYE KÖYÜ DORÜS SOKAK NO:27/0MERKEZ / DÜZCE / TÜRKİYE

Certificate No.: SISTURCE052020822

Issue Date (Original): 12.05.2020 Issue Date(Latest): 12.05.2020

Expiry Date: 11.05.2021

This Certificate is issued under the following conditions:

1.It applies only to the above referenced models of the medical devices.

2.It does not imply that the SIS has performed any surveillance or control of their manufacture.

3. The manufacture is obligated to assure conformity of all in medical devices of

the respective model to type assessed by the mean of this certificate.

4. The certificate remains valid until the manufacturing condition, the quality system or relevant legislation are changed.

5.After fulfilling of the relevant EU legislation requirements, the manufacture shall affix to each medical device, of the above referenced models, the CE-marketing according to this example:



Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid.

Corporate office(SIS):- Plot No. 1539, 2nd Floor, Sector-4, Gurgaon-122001, Haryana, India. International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047. Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91-9654721646 Web:- http://www.siscertifications.co.in, www.siscertifications.com of this certificate can be verified on "http://www.siscertifications.co.in".







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CE ATTESTATION OF CONFORMITY

Related Directives:

PERSONAL PROTECTIVE EQUIPMENT (PPE) DIRECTIVE 2016/425 (EU) KİŞİSEL KORUYUCU DONANIM YÖNETMELİĞİ 2016/425 (EU)

Class / Sınıf: CATEGORY 1 / KATEGORİ 1

Description of Product:

PROTECTIVE GOWN / KORUYUCU ÖNLÜK PROTECTIVE COVERALL / KORUYUCU TULUM

Color:

WHITE / BEYAZ

Trade Mark: SMART

Manufactured by

ALİYA GİYİM TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ ISLAHİYE KÖYÜ DORÜS SOKAK NO:27/0MERKEZ / DÜZCE / TÜRKİYE

Certificate No.: SISTURCE052020823 Issue Date (Original): 12.05.2020 Issue Date(Latest): 12.05.2020 Expiry Date: 11.05.2021

CE

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate is issued under the following conditions:

1.It applies only to the above referenced models of the medical devices.

- 2.It does not imply that the SIS has performed any surveillance or control of their manufacture.
- 3. The manufacture is obligated to assure conformity of all in medical devices of
- the respective model to type assessed by the mean of this certificate.
- 4.The certificate remains valid until the manufacturing condition, the quality system or relevant legislation are changed .
- 5. After fulfilling of the relevant EU legislation requirements, the manufacture shall affix to each medical device, of the above referenced models, the CE-marketing according to this example:



Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.





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The status of this certificate can be verified on "http://www.siscertifications.co.in".

