



SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

CE

CE ATTESTATION OF CONFORMITY

Related Directives :  
MEDICAL DEVICES 93/42/EEC-----TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

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

Description of Product :

MASK  
MASKE

Product Model / Ürün Modeli:

FFP 2 / N 95

Manufactured by

OSAKA MEDİKAL MAKİNE SANAYİ VE TİCARET LİMİTED ŞİRKETİ  
TOPÇULAR MAH. TORNACI SOK. ATC APT. NO:20 A EYÜPSULTAN / İSTANBUL / TÜRKİYE

Certificate No.: SISTURCE0820201482

Issue Date (Original): 22.08.2020

Issue Date(Latest): 22.08.2020

Expiry Date: 21.08.2021

CE

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:

  
Managing Director



**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 Compliance 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](http://www.siscertifications.com)  
The status of this certificate can be verified on "<http://www.siscertifications.co.in>".

Issue No.: 01

CERTIFICATE OF COMPLIANCE





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

CE

CE ATTESTATION OF CONFORMITY

Related Directives :  
MEDICAL DEVICES 93/42/EEC-----TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

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

Description of Product :

MASK  
MASKE

Product Model / Ürün Modeli:

FFP2 WITH VALVE / N 95  
FFP2 VENTİLLİ / N 95

Manufactured by

OSAKA MEDİKAL MAKİNE SANAYİ VE TİCARET LİMİTED ŞİRKETİ  
TOPÇULAR MAH. TORNACI SOK. ATC APT. NO:20 A EYÜPSULTAN / İSTANBUL / TÜRKİYE

Certificate No.: SISTURCE0820201483

Issue Date (Original): 22.08.2020

Issue Date(Latest): 22.08.2020

Expiry Date: 21.08.2021

CE

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:

*Managing Director*



**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 Compliance 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](http://www.siscertifications.com)  
The status of this certificate can be verified on "<http://www.siscertifications.co.in>".

Issue No.: 01

CERTIFICATE OF COMPLIANCE

