



SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

CE

CE ATTESTATION OF CONFORMITY

Related Directives :

MEDICAL DEVICES 93/42/EEC & 2007/47/EC

TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC & 2007/47/EC

Class / Sınıf: CATEGORY 1 / KATEGORİ 1, TYPE 2R / TİP 2R

Description of Product :

DISPOSABLE THREE LAYER SURGICAL FACE MASK WITH EARLOOP
TEK KULLANIMLIK ÜÇ KATLI CERRAHİ MASKE, LASTİKLİ

Filter Grade / Filtre Sınıfı :

FFP1, FFP2

Regulations Applied acc. To Harmonized Standards:

EN 149:2001+A1:2009, EN 14683:2019+AC:2019, ISO 9001:2015, ISO 13485:2016

Manufactured by

PLATİN MODA TASARIM TEKSTİL
SANAYİ VE DIŞ TİCARET LİMİTED ŞİRKETİ
ÇOBANÇEŞME MAH. SELVİ SOK. NO:3 İÇ KAPI NO: 31
BAHÇELİEVLER / İSTANBUL / TÜRKİYE

Certificate No.: SISTURCE052020655

Issue Date (Original): 08.05.2020

Issue Date(Latest): 08.05.2020

Expiry Date: 07.05.2021

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:

CE

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 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.

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The status of this certificate can be verified on "http://www.siscertification.com".

Issue No.: 01

CERTIFICATE OF REGISTRATION

