

EC DECLARATION OF CONFORMITY



We, APEX TEKNİK TEKSTİL VE SAĞLIK ÜRÜNLERİ SAN. TİC. LTD. ŞTİ.

herewith declare that the following described product meets the provisions of the following directives. All supporting documentation is retained under the premises of the manufacturer.

PRODUCT : DISPOSABLE FACE MASK

MODEL : TIE ON, EARLOOP

CLASS : CLASS 1

APPLICABLE EC DIRECTIVES :
93/42/EEC MEDICAL DEVICE DIRECTIVE

APPLICABLE STANDARDS :
TS EN 14683 SURGICAL MASK
TS EN 15223-1 LABEL SYMBOLS OF MEDICAL DEVICES
TS EN ISO 14971 APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
TS EN ISO 10993 series BIOCOMPATIBILITY

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