

Masque chirurgical pédiatrique type 1 enfants 5 à 12 ans

Réf : AJMAKID



Boîte contenant 5 sachets de 10 masques

Masque de protection pédiatrique idéal pour les établissements d'accueil des enfants pour les enfants : garderies, écoles maternelles et primaires, services pédiatriques en hôpital, etc.

Description :

Le masque chirurgical pédiatrique type 1 pour enfant de 5 à 12 ans offre une efficacité de filtration bactérienne (BFE) à 95% et particules de type 1 et est fabriqué en matière douce pour un port confortable.

Il est composé de 3 couches pour une protection respiratoire renforcée.

Caractéristiques techniques :

- **Equipement :**
 - 3 couches pour une protection respiratoire renforcée
 - Elastiques auriculaires
 - Barrette nasale intégrée
- **Matériaux :**
 - Fabriqué en meltblown (propriétés filtrantes)
 - Spunbond non-tissé (confort respiratoire optimal), textile aux fibres plus grosses (matériau support) ;
 - Sans latex.
- **Coloris :** bleu.
- **Dim. :** L 145 x H 95 mm
- **Conditionnement :** conditionnés par boîte de 50 masques, en cinq sachets de 10 masques dans la boîte.
- **Type de dispositif :** masque chirurgical à usage unique.
- **Conformité :** conformes à la norme EN 14683 : 2019.

EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2020/16042020.7

**CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of
Suining Motianshidai Medical Equipment Co.,Ltd.
Zone B, 2f, building 3, Zongyi Road, Xining District, Suining Economic and Technological Development Zone, Sichuan Province,China**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/540/2020**



Issued on: 17/04/2020



Authorized Signatory
CMC Medical Devices & Drugs SL

Valid until: 16/04/2021

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ANNEX I Medical Device Products

Disposable Medical Mask (Non-Esterile)



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Suining Motianshidai Medical Equipment Co., Ltd

CE Technical documentation of Face Mask

Document No.: HCE20200528

Issue Date: 2020.05.28

APPROUVÉ
Par Delmaire , 15:31, 27/08/2020

Declaration of conformity

Manufacturer: Suining Motianshidai Medical Equipment Co., Ltd

Add: Zone B, 2F, Building F, Zongyi Road, Xining District, Suining Economics and technological Development Zone, Sichuan Province, China.

Tel: +86-139234456330

Email: 275209020@qq.com

Product Name: Disposable medical face mask –SZAK11-1

Classification and relevant rule: I according to ANNEX IX, rule 1

UMDNS code: 12458

CE conformity assessment route: Annex VII

We here with declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the promise of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)

The device is in conformity with the following standard
EN14683:2019 TYPE I

Test Report : N° 60378924001 TUV Rheinland



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