

# DAFANG®

## Type IIR Disposable Medical Face Mask



- Type IIR Disposable Medical Surgical Face Mask
- Protection for mouth, nose and jaw against pathogenic micro-organism, body fluids and particles.
- Ear-loop elastic straps
- Bacterial efficiency  $\geq 98\%$
- Non-oily particle filtration efficiency  $\geq 30\%$
- Penetration tested at 2mL synthetic blood at 16.0kPa
- 20 sealed in a pack, 2 packs per box, 50 boxes per outer
- CE Certified
- Manufactured to ISO13485-2016
- EN14683: 2019



Medical Device  
Product Registration No.: 豫械注准20172641026  
Product Technical Requirement No.: 豫械注准20172641026  
Executive Standard: YY0469-2011

DAFANG

www.xdafang.com

Production License No.: 豫食药监械生产许20090060号



# Disposable Medical Surgical Mask

一次性医用外科口罩

Specification: Flat bandage/Flat ear hanging

BFE: ≥98% • EN 14683:2019 • TYPE IIR • ISO 13485

40Pcs



## EU Declaration of Conformity

Manufacturer: Dafang Medical Treatment Co., Ltd.  
Dingluan Dafang Industrial Park, Changyuan County, Henan  
Province, China

European Representative: CMC Medical Devices & Drugs S.L.  
Horacio Lengo N° 18, CP 29006, Málaga, Spain  
SRN: /

Product Name: Disposable surgical Face Mask  
Specification: 17.5cm×9.5cm  
GMDN Code: 35177  
UMDN Code: 12-458

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY  
following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the  
transposition into national law, the provisions of the following EU Regulation  
and Standards. All supporting documentations are retained under the  
premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of  
conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of  
5 April 2017 on medical devices, amending Directive 2001/83/EC,  
Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and  
repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013,  
EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO  
10993-5:2009, ISO 10993-10:2010, MDCG 2019-15.

Signature:

Name:  
Position:

Fu Xiao  
General Manager

Place/date:

Changyuan, Mar. 24, 2020

