## **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 >= 98%
- Non-oily particle filtration efficiency >=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

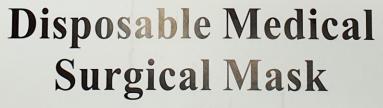




Product Technical Requirement No.: 豫械注准20172641026

Executive Standard: YY0469-2011

DAFANG



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

**( (2)** 



## EU Declaration of Conformity

Manufacturer:

Dafang Medical Treatment Co., Ltd.

Dingluan Dafang Industrial Park, Changyuan County, Henan

Province, China

European

CMC Medical Devices & Drugs S.L.

Representative:

Horacio Lengo Nº 18, CP 29006, Málaga, Spain

SRN:

Product Name:

Disposable surgical Face Mask

Specification:

17.5cm×9.5cm

GMDN Code: UMDN Code:

35177 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:

Pu Xiao

Position:

General Managet

Place/date:

hangyuan, Mar.

File No.: DF/CE01-01, ver.A/0