# *MASCHERINE CHIRURGICHE*

## Elenco dei dispositivi medici

**Criteri di ricerca:**
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario: **MABE S.R.L.**
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

## Elenco dispositivi individuati

Dati aggiornati al:11/10/2020

| DISPOSITIVO MEDICO/ASSEMBLATO | | | | | |
|---|---|---|---|---|---|
| TIPOLOGIA DISPOSITIVO | IDENTIFICATIVO DI REGISTRAZIONE BD/RDM | ISCRITTO AL REPERTORIO | CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE | NOME COMMERCIALE E MODELLO | CND |
| Dispositivo | 1951555 | N | 700171SH001Q | DISPOSABLE MASK OMEY | T020601 - MASCHERINE CHIRURGICHE STANDARD |

| | | | FABBRICANTE/ASSEMBLATORE | | | | |
|---|---|---|---|---|---|---|---|
| CLASSE CE | DATA PRIMA PUBBLICAZIONE | DATA FINE IMMISSIONE IN COMMERCIO | RUOLO AZIENDA | DENOMINAZIONE | CODICE FISCALE | PARTITA IVA/VAT NUMBER | NAZIONE |
| I - Classe I non sterile e senza funzioni di misura | 09/05/2020 | | FABBRICANTE | TONGLU KAIQI KNITTED GARMENTS | | | CN |
| | | | MANDATARIO | MABE S.R.L. | 02969620133 | 02969620133 | IT |

UNIVERSAL
CERTIFICATION

# ATTESTATION OF CONFORMITY

## Certificate Nr: MDD - 101

*In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,*

the products manufactured for

**MABE SRL UNIPERSONALE**

VIA INDUSTRIA N.18 22070 LUISAGO COMO - ITALY

Manufactured at

**TONGLU KAIQI KNITTED GARMENTS CO. LTD**

NO.253 JINGCHENG RD, FANGBU INDUSTRIAL AREA TONGLU COUNTY
HANGZHOU CITY ZHEJIANG PROVINCE, CHINA

**EN 14683:2019+AC:2019 Medical Face Masks**

**Brand Name :** OMEY
**Model :** DISPOSABLE MASK
Type II
are tested according to the following initial type tests by the manufacturer

Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

For the assessment of conformity, the following documents were also applied to:
Results of laboratory tests Ekoteks Testing Laboratory BFE
Results of laboratory tests Ekoteks Testing Laboratory Differential Pressure
Results of laboratory tests Ekoteks Testing Laboratory Microbial Cleanliness

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spread to patients. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table 1) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 06/05/2020 and valid until 05/05/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

CE

ISTANBUL –06/05/2020

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR