DECLARACIÓN UE DE CONFORMIDAD

Distribuidor: JBM CAMPLLONG, S.L.U.

Dirección: CIM La Selva – Crta. Aeroport Km 1.6 Nave 2.2, 17185 Vilobí d'Onyar

CIF (VAT number): ESB17419292

Descripción del producto: MASCARILLA QUIRÚRGICA IIR

Referencia del fabricante: ENM-313

Referencia del distribuidor: 53907

El objeto de la declaración es conforme con el Reglamento de Productos Sanitarios (UE) 2017/745 y las siguientes normas:

Norma	Título	Edición/Fecha
EN14683	Mascarillas quirúrgicas. Requisitos y métodos de ensayo.	2019+AC:2019
EN ISO 15223-1	Productos sanitarios. Símbolos que deben utilizarse en las etiquetas de los productos sanitarios, en el etiquetado y en la información que debe suministrarse. Requisitos generales	2016

Firmado:

JBM CAMPLLONG, S.L.
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Eduard Godoy

Director departamento de compras

En Girona, a 31 de diciembre de 2021

JBM CE

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UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-267

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,

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name : ENMED
Model : ENM-313
Type IIR
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 Laboratuvar Testing Laboratory Bacterial Filtration Efficiency, Microbial Cleanliness, Differential Pressure and Splash Resistance Pressure tests.

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 25/09/2020 and valid until 24/09/2021 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.

ISTANBUL –25/09/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be conducted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

EU DECLARATION OF CONFORMITY

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name : ENMED
Model : ENM-313
Type IIR

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Bavterial filtration efficiency
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Differential Pressure
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Splash Resistance Pressure

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered

MEASURES TO ENSURE CONFORMITY

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

General Manager
25/09/2020