

UNIVERSAL ITALY



ATTESTATION OF CONFORMITY

Certificate Nr: MDD-13/IT

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

the products manufactured for

DISTRIBUZIONE JUNIOR S.r.l.

at the following address

VIA PACE, 25/6 – 80047 SAN GIUSEPPE VESUVIANO (NA) -ITALY

Manufactured at

XIANTAO CITY CANCAN NONWOVEN PRODUCTS CO., LTD

GROUP 3, SAN WAN VILLAGE, SANFUTAN TOWN, XIANTAO CITY, HUBEI PROVINCE, CHINA

EN 14683:2019+AC:2019 Medical Face Mask

Brand Name: **ENHANCE - Model: EH3640 Surgical Junior 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 by NPT Testing for Laboratory BFE, Microbial Cleanliness and Differential Pressure

UNIVERSAL ITALY 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 I) 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.

Date issued :16/09/2020

Date expire: 15/09/2021

ROME 16/09/2020

Italy Manager



Verify the validity with the QR code and Universal register

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 audit updating the publication date without changing the certificate number.