

# UNIVERSAL CERTIFICATION

## ATTESTATION OF CONFORMITY

Certificate Nr: MDD-06/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*

**TECNOSTEEL S.R.L.**

*at the following address*

**Via Trento, 7 – 36025 Noventa Vicentina (VI) – Italy**

*Manufactured at*

**SV MEGA SHPK**

**Rruga Egnatia, Lagjia nr.3, Pallati nr. 452 Zone Kadastrale 8514, Durres Albania**

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

**Brand Name: SVMEGA - Model: SV001 Surgical 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 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.*

*This certificate is issued on 09/07/2020 and valid until 08/07/2021 with the conditions that no change has been made with the product references and no change in the production processor not suspended or withdrawn for any reason.*



ROME 09/07/2020

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*How Maurolo*  
Italy Manager

Verify the validity with the QR code