



UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1605

CARINE EUROPE GMBH

Ammannstrasse No:12 86167 Augsburg GERMANY

Manufacturer:

Aydağ Tedavi ve Sağlık Hizmetleri Sanayi ve Ticaret A.Ş.
Orta Mah. Menderes Cad. No:7/3 K1 Bayrampaşa İstanbul TURKEY

It is certified that the manufacturer's technical file (Dated 25.08.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment

Brand Name: Carine Medical, Model: CRM-PGA-SC

Protective Shoe Cover as a protective clothing for the part of body Type PB-[6]-B, manufactured from white laminated polypropylene non-woven fabric, inside bound seams and elastic ankle parts.

The PPE is available in 1 standard size

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)

EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited life clothing,

EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B.

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with the below requirements;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on 23/10/2020 and will be valid for 5 years from the issue date.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

