

UNIVERSAL

CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1779

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-PCA-300

Protective overall manufactured from laminated polypropylene non-woven fabric with hood, inside overlock seams and seams are covered by hotmelt tape, elastic cuff, ankle and waist, zipper and zipper flap. The overall is available in 6 nominal sizes.

The following harmonised standards have been applied:

- EN ISO 13688:2013, (General requirements for protective clothing)
- EN 14605:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 3, Type 4, limited wear life clothing,
- EN ISO 13982-1:2004/A1:2010, (Chemical protective clothing providing protection to the full body against airborne solid particulates) Type 5, limited wear life clothing,
- EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 6, limited wear life clothing,
- EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type 3-B, 4-B, 5-B, 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 11/12/2020 and will be valid for 5 years from the issue date.

CE
2163


Suat KACMAZ
UNIVERSAL CERTIFICATION
Director



Verify the validity with the QR Code