



EU DECLARATION OF CONFORMITY

Product - Personal Protective Equipment (PPE):

Isolation Gown – Category III, Type PB 6-B

REF: CRM400-IGA-100

PPE Category: III

Manufacturer: CARINE Europe GmbH, Ammannstraße 12, 86167 Augsburg, Germany

We herewith declare under our sole responsibility that above-mentioned products meet requirements of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC and Standards: EN 14126:2003, EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 1149-5:2018.

The EU declaration of conformity has been drawn up following appropriate conformity assessments procedures. As a Personal protective equipment category III – after drawing up technical file and after appropriate conformity assessment in accordance with art. 15 in connection with art. 19 of the PPE Regulation.

Isolation Gown (REF: CRM400-IGA-100), as PPE, was the subject of EU-type examination. Certificate number 115-21-08 was issued by notified body no 2841 – MNA Laboratuvarları Tic. Ltd. Şti., Küçükbakkalköy Mahallesi Yenidoğan Cad. No: 21, Ataşehir / İSTANBUL / TURKEY on 12.07.2021.

The PPE is subject to the conformity assessment procedure - conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body no 2841 – MNA Laboratuvarları Tic. Ltd. Şti., Küçükbakkalköy Mahallesi Yenidoğan Cad. No: 21, Ataşehir / İSTANBUL / TURKEY.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed on behalf of manufacturer.

Date:

13.08.2021

Place:

Augsburg

Manufacturer's representative:

Katherine Alperen

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