

EU DECLARATION OF CONFORMITY



The manufacturer, CARINE Europe GmbH, Ammannstr. 12, 86167 Augsburg, Germany, declares under their sole responsibility, that the product mentioned below complies with the requirements of 93/42/EEC Medical Devices Directive on harmonization of laws, regulations and administrative documentation of Member States on Medical Devices and European Commission directive 2007/47/EC amending Medical Devices Directive dated 05 September 2007.

Products:

- Surgical Gowns, Medical Product Class 1
- Scrub Suits, Medical Product Class 1
- Isolation Gowns, Medical Product Class 1
- Medical Gowns, Medical Product Class 1
- Shoe Covers, Medical Product Class 1
- Bouffant Caps, Medical Product Class 1

The following harmonised standards have been applied:

- EN 13795-1:2019
- EN ISO 15223-1:2016
- EN 1041:2008+A1:2013

Augsburg, 29.10.2020


CARINE EUROPE GMBH
Ammannstraße 12 - 86167 Augsburg
Tel. +49 821 455 60 525 - Fax +49 821 455 60 524
UST-ID: 296024927 - HRS 213594