

**TECHNICAL FILE**  
**NON-STERILE MEDICAL PRODUCTS**  
**EC DECLARATION**

Document No	TF.03-B.4.1.3
Issue Date	02.12.2021
Revision Date	
Revision No	
Page No	1 / 2

**EU Medical Device Regulation 2017/745**  
**Declaration of Conformity**

Manufacturer Name	Carine Europe GMBH
Manufacturer Address	Ammannstraße 12 86167 Augsburg- Germany
Manufacturer SRN	DE-MF-000014511
Contract Manufacturer's Name and Address (* If applicable)	Aydağ Tedavi ve Sağlık Hiz. San. Tic. A.Ş. Yenibosna Merkez Mah. Cemal Ulusoy Cd. No:57/2 34197 Bahçelievler/ İstanbul Turkey
Product Group	Non Sterile Disposable Medical Gowns
Product Name	- Non Sterile Disposable Scrub Suits, Scrub Tops and Scrub Pants - Non Sterile Disposable Thermal Jackets and Thermal Suits
Descriptive Information and Explanations of the Product	See Annex I
Conformity Assessment Procedure (*)	<input checked="" type="checkbox"/> Annex-IV (Annex II & III) Declaration of conformity
	<input type="checkbox"/> Annex-IX (Article I & III) Quality Management System
	<input type="checkbox"/> Annex-IX (Article II) Technical Documentation Evaluation
	<input type="checkbox"/> Annex-X Type Examination
	<input type="checkbox"/> Annex-XI (Chapter A) Production Quality Assurance
	<input type="checkbox"/> Annex-XI (Chapter B) Product Verification
(Additions executed in the product evaluation are marked)	
Other EU Legislation / Common Specifications / Harmonized Standards to which the product complies	(EU) 2017/745, EN ISO 14971:2019, EN ISO 13485:2016, ISO 15223-1:2021, EN 62366-1:2015, EN ISO-10993-1:2018, EN ISO-10993-5: 2009, EN ISO-10993-10:2021, EN 13795:2019,

As Carine Europe GmbH, we declare under our sole responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements set out in the Regulation for these devices are fulfilled.

Signature Date and Place :

Valid Date (if applicable):

AUGSBURG, 28.12.2021

Approver : Katherina ALPEREN / GENERAL MANAGER

[Signature and Seal/Stamp]



<b>Document No</b>	TF.03-B.4.1.3
<b>Issue Date</b>	02.12.2021
<b>Revision Date</b>	
<b>Revision No</b>	
<b>Page No</b>	2 / 2

[illegible]