

TECHNICAL FILE
NON-STERILE MEDICAL PRODUCTS
EC DECLARATION

Document No	TF.03-B.4.1.3
Issue Date	02.12.2021
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EU Medical Device Regulation 2017/745
Declaration of Conformity

Manufacturer Name	Carine Europe GMBH		
Manufacturer Adress	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 (*) (Additions executed in the product evaluation are marked)	<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
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]



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This EU Declaration of Conformity covers ONLY products with the following catalog/reference numbers:

Reference Number	Product Name/Description	Purpose of usage	GMDN Code	EMDN Code	Class/Classification Rule (*)	Basic UDI-DI
CRM-5100	Non Sterile Disposable Scrub Suits	Disposable products are mainly intended to provide a clean barrier in sterile environments and other clinical treatment environments such as emergency rooms, labor and delivery areas, and intensive care units.	58382	T0205	Class I Rule 1	4061404CRM-510055
CRM-5200	Non Sterile Disposable Scrub Tops					4061404CRM-52005A
CRM-5110	Non Sterile Disposable Scrub Pants					4061404CRM-511058
CRM-5210	Non Sterile Disposable Thermal Jackets					4061404CRM-52105D
CRM-5120	Non Sterile Disposable Thermal Suits					4061404CRM-51205B
CRM-5220						4061404CRM-52205G
CRM-5130						4061404CRM-51305E
CRM-5230						4061404CRM-52305K
CRM-5140						4061404CRM-51405H
CRM-5240						4061404CRM-52405N