CARINE Medical & Personalized Health	TECHNICAL FILE NON-STERILE MEDICAL PRODUCTS EC DECLARATION	Document No	TF.03-B.4.1.1
		Issue Date	02.12.2021
		Revision Date	
		Revision No	
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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 Name	Non Sterile Disposable Medical Gowns - Non Sterile Disposable Surgical Gowns		
Catalog/Referance No	CRM-SGA		
Intended Use	A surgical gown is a personal protective garment intended to be worn by health care personnel during surgical procedures to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate matter.		
Basic UDI-DI	4061404CRM-SGAG9		
Product Classification and Rule	Class I / Rule 1		
GMDN Code	35091		
EMDN Code	T0204		
Conformity Assessment Procedure (*) (Additions executed in the product evaluation are marked)	■	Annex-IV (Annex II & III)	Declaration of conformity
	☐	Annex-IX (Article I & III)	Quality Management System
	☐	Annex-IX (Article II)	Technical Documentation Evaluation
	☐	Annex-X	Type Examination
	☐	Annex-XI (Chapter A)	Production Quality Assurance
	☐	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 : 12.12.2021
Valid Date (if applicable): Augsburg

CARINE
Medical & Personalized Health

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Approver : Katherine ALPEREN / GENERAL MANAGER
(Signature and Seal/Stamp)