CARINE Medical & Personalized Health	TECHNICAL FILE NON-STERILE MEDICAL PRODUCTS EC DECLARATION	Document No	TF.03-B.4.1.8
		Issue Date	14.01.2022
		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		
Product Name	Non Sterile Disposable Visitor Boats		
Catalog/Referance No	CRM-6130		
Intended Use	Protective boats are primarily used to cover a portion of the patient's anatomy during an examination or non-surgical treatment procedure at home or in a healthcare facility to prevent contamination/cross-contamination. This is a disposable device.		
Basic UDI-DI	4061404CRM-61305M		
Product Classification and Rule	Class I / Rule 1		
GMDN Code	61048 - Patient examination/treatment drape, single-use A non-sterile, noninvasive flat sheet designed to cover a portion of a patient's anatomy during an examination or non-surgical treatment procedure in the home or healthcare facility primarily to prevent soiling/cross-contamination; it is not intended for surgical use. This is a single-use device.		
EMDN Code	T0210 – Non Surgical Drapes		
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 :
Valid Date (if applicable):
14.01.2022, AUGSBURG

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

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