

	<b>TECHNICAL FILE</b>  <b>NON-STERILE MEDICAL PRODUCTS</b>  <b>EC DECLARATION</b>	<b>Document No</b>	TF.03-B.4.1.9
		<b>Issue Date</b>	03.03.2022
		<b>Revision Date</b>	
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## EU Medical Device Regulation 2017/745 Declaration of Conformity

<b>Manufacturer Name</b>	Carine Europe GMBH		
<b>Manufacturer Address</b>	Ammannstraße 12, 86167 Augsburg- Germany		
<b>Manufacturer SRN</b>	DE-MF-000014511		
<b>Product Group</b>	Non Sterile Disposable Medical Bedding		
<b>Product Name</b>	- Non Sterile Disposable Medical Bedding Blue (Pillow, Quilt Cover, Bed Sheet) (50111132) - Non Sterile Disposable Medical Bedding Blue (Pillow, Quilt Cover, Bed Sheet) (50111133)		
<b>Descriptive Information and Explanations of the Product</b>	See Annex I		
<b>Conformity Assessment Procedure (*)</b>  (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
<b>Other EU Legislation / Common Specifications / Harmonized Standards to which the product complies</b>	(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, 04.03.2022

**Approver : Katherine 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
50111132	Non Sterile Disposable Medical Bedding Blue (Pillow 70x80 cm, Quilt Cover 160x200 cm, Bed Sheet 160x240 cm)	It is designed as a disposable product consisting of a 3-piece cover, which aims to protect the patient bed from contamination and provide clean, non-irritating contact surfaces to the person in the bed.	47456	T030502	Class I Rule 1	406140450111132ZM
50111133	Non Sterile Disposable Medical Bedding Blue ( Pillow 70x80 cm, Quilt Cover 140x200 cm, Bed Sheet 140x240 cm )					