

**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		
Product Group	Non-Sterile Disposable Medical Bedding		
Product Name	- Non-Sterile Disposable Medical Bed Sheet		
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):

Approver: Katherine ALPEREN / GENERAL MANAGER
[Signature and Seal/Stamp]

AUGSBURG, 09.05.2022


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

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Revision Date	
Revision No	01
Page No	2 / 2

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
4061404006568	Non-Sterile Disposable Medical Bed Sheet	It is designed as a disposable product, 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	4061404006568NZ
4061404006575	Non-Sterile Disposable Medical Bed Sheet	It is designed as a disposable product, 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	4061404006575NW