

TECHNICAL FILE
NON-STERILE MEDICAL PRODUCTS
EC DECLARATION

Document No	TF.03-B.4.1.10
Issue Date	04.03.2022
Revision Date	
Revision No	01
Page No	1 / 2

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 Emergency Blanket		
Product Name	- Non Sterile Disposable Emergency Blanket (One Side Gold, One Side Silver) - Non Sterile Disposable Emergency Blanket (One Side Silver, One Side Silver)		
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,		

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
CRM-RB-01S	Non Sterile Disposable Emergency Blanket (One Side Gold, One Side Silver)	It is used to prevent further loss of the patient's body temperature.	10416	T030301	Class I Rule 1	4061404CRM-RB-01STX
CRM-RB-02GS	Non Sterile Disposable Emergency Blanket (One Side Silver, One Side Silver)					4061404CRM-RB-02GS95