

**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	Underpads		
Product Name	- Underpad Premium		
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, ISO 15621:2017		

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 (EU) 2017/745 are fulfilled.

Signature Date and Place : 14.06.22, Augsburg
Valid Date (if applicable):

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



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

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Revision Date	
Revision No	
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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-PUP-800-60-30	UNDERPAD PREMIUM 60*60	A disposable drape used to collect urine and faeces from an incontinent adult patient. Non-active, non-implantable devices for incontinence care, not worn on the body	11239	T04010201	Class I Rule 1	4061404CRM-PUP-8006030CP
CRM-PUP-1000-60-30						4061404CRM-PUP-100060303T
CRM-PUP-1200-60-30						4061404CRM-PUP-120060304V
CRM-PUP-1400-60-30						4061404CRM-PUP-140060305X
CRM-PUP-1600-60-30						4061404CRM-PUP-160060306Z
CRM-PUP-800-90-30	UNDERPAD PREMIUM 60*90					4061404CRM-PUP-8009030DC
CRM-PUP-1000-90-30						4061404CRM-PUP-100090304G
CRM-PUP-1200-90-30						4061404CRM-PUP-120090305J
CRM-PUP-1400-90-30						4061404CRM-PUP-140090306L
CRM-PUP-1600-90-30						4061404CRM-PUP-160090307N