

	TECHNICAL FILE NON-STERILE MEDICAL PRODUCTS EC DECLARATION	Document No	TF.03-B.4.1.12
		Issue Date	18.06.2022
		Revision Date	
		Revision No	
		Page No	1 / 2


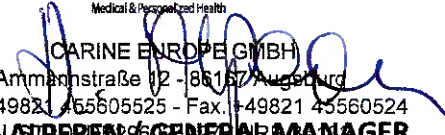
EU Medical Device Regulation 2017/745 Declaration of Conformity

Manufacturer Name	Carine Europe GmbH		
Manufacturer Address	Ammannstraße 12, 86167 Augsburg - Germany		
Manufacturer SRN	DE-MF-000014511		
Product Group	Surgical Cap		
Product Name	- Surgical Cap With Tie On - Surgical Cup With Elastic Band		
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 : 21.06.2022

Valid Date (if applicable):


 Medical & Personalized Health

 CARINE EUROPE GMBH
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Approver: Katherine ALPERIN, GENERAL MANAGER
[Signature and Seal/Stamp]



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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
CRM-F4	Surgical Cap With Tie On	It is designed to be worn by the surgical personnel to protect both the patient and the surgical personnel themselves from the contamination of microorganisms, body fluids and particulate material during the surgical operation and to be used as a hygienic head cover in other health institutions.	32297	T0207	Class I Rule 1	4061404CRM-F4EG
CRM-F5	Surgical Cup With Elastic Band					4061404CRM-F5EJ Surgical Cap