

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

Document No	TF.03-B.4.1.5
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**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	
Contract Manufacturer's Name and Address (* If applicable)	Aydağ Tedavi ve Sağlık Hiz. San. Tic. A.Ş. Yenibosna Merkez Mah. Cemal Ulusoy Cd. No:57/2 34197 Bahçelievler/ İstanbul Turkey	
Product Name	Non Sterile Disposable Face Mask - TYPE IIR / TYPE II	
Catalog/Reference No	CRM-M01 / CRM-M02	
Intended Use	Disposable surgical masks are designed to help the wearer prevent the spread of respiratory droplets produced by coughing or sneezing, it also features a splash-resistant layer of fabric that, in turn, protects the wearer from splashes of blood and bodily fluids.	
Basic UDI-DI	4061404CRM-M01CB	
Product Classification and Rule	Class I / Rule 1	
GMDN Code	35177	
EMDN Code	T020604	
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 14683:2019	

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 : 13.01.2022, Augsburg  
Valid Date (if applicable):



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USt-Id. DE20604927 - HRB 35132

Approver : Katherine ALPEREN / GENERAL MANAGER

(Signature and Seal/Stamp)