CARINE
Medical & Personalized Health

CARINE EUROPE GMBH
Ammannstraße 12 86167 Augsburg- Germany

DECLARATION OF CONFORMITY

CARINE EUROPE GMBH is assessed by KIWA BELGELENDİRME HİZMETLERİ A.Ş. Notified Body N° 1984. This declaration is made in accordance with Annex VII of the Medical Devices Directive 93/42 EEC and Amendment 2007/47/EEC.

Notified Body	KIWA BELGELENDİRME HİZMETLERİ A.Ş.
Notified Body Address	İTOSB ISTANBUL TUZLA ORGANİZE SANAYİ BÖLGESİ 9. CADDE NO:15 TEPEÖREN MEVKİİ ANKARA ASFALTI TUZLA-İSTANBUL/TÜRKİYE
Notified Body Number	1984

CE Certificate No	**1984-MDD-21-838**	**Publication Date**	**24.05.2021**
		Expiry Date	**27.05.2024**
Conformity Assessment Route	Annex II (without Section 4)		

CARINE EUROPE GMBH, declares that under our sole responsibility that the products below to which this declaration relates are in conformity with the following standards or other regulatory laws following the provisions of 93/42/EEC Medical Device Directive amended by 2007/47/EC.

Applied standard list on the products is given in Annex I of this declaration.
Product List is given in Annex II of this declaration

Place: Germany

Name Surname Title - Date	Name Surname Title-Date	Date of Issue
Evin Yılmaz Quality Management Rep.	Katherine Alperen General Manager	**12.10.2021**

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Declaration of Conformity – Annex I

Applied Standard List

Standard/Document No	***Standard/Document Name***
93/42/EEC:2007	*Medical Device Directive*
MEDDEV 2.7.2:2016	*Guidelines for competent authorities for making a validation/assessment of a clinical investigation application under directives*
MEDDEV 2.7.1:2016	*Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/ECC and 90/385/EEC*
MEDDEV 2.4.1:2010	*Classification of medical devices*
MEDDEV 2.2.3:1998	*"Use-by" date for medical devices*
MEDDEV 2.12/1:2013	*Guidelines on a Medical Device Vigilance System*
MEDDEV 2.12/2:2012	*Post Market Clinical Follow-up Studies*
EN ISO 14971:2019	*Medical devices — Application of risk management to medical devices*
EN ISO 13485:2016	*/ Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*
EN ISO 15223-1:2016	*Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*
EN 62366-1:2015	*Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*
EN ISO-10993-1: 2009 AC:2010 EN: 2020	*Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*
EN ISO-10993-5:2009	*Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
EN ISO-10993-10:2014	*Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization*
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes /*
EN ISO 14698-1:2004	*Cleanrooms and associated controlled enviroments - Biocontamination Control - Part 1: General principles and methods*
EN ISO 14698-2:2005	*Cleanrooms and associated controlled enviroments - Biocontamination Control - Part 2: Evaluation and interpretation of biocontamination data*
EN ISO 14644-1:2015	*Cleanrooms and associated controlled environments- Part 1: Classification of air cleanliness by particle concentration*
EN ISO 14644-2:2015	*Cleanrooms and associated controlled environments- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

EN ISO 14644-3:2019	*Cleanrooms and associated controlled environments - Part 3: Test methods*
EN ISO 14644-4:2001	*Cleanrooms and associated controlled environments- Part 4: Design, construction and start-up*
EN ISO 14644-5:2004	*Cleanrooms and associated controlled environments - Part 5: Operations*
EN ISO 11135: 2014 '+A1:2019	*Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices*
EN 13795:2019	*Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns*

Declaration of Conformity – Annex II

Product Group List

Product List is given as Technical File – Annex II

NAME	*CLASS*	*RULE*	*GMDN CODE*	*STERILIZATION*
Sterile Single Use Surgical Surgical Gown	Is	1	35778	Sterile
Sterile Single Use Surgical Drapes	Is	1	47783	Sterile
Sterile Single Use Surgical Drape – Gown Sets	Is	1	47783	Sterile
Sterile Single Use Surgical Coveralls	Is	1	65414	Sterile
Sterile Single Use Foot and Head Drapes	Is	1	47783	Sterile
Sterile Single Use Surgical Accessories (Tool Table Drape, Mayo Table Drape, Extremity Drape, Hand/Foot Drape, Scopy Sheath, Stokinette, Floroscopy Sheath,Leg Sheath, Microscope Sheath, Camera Sheath))	Is	1	47783 43970 35374 12535 37450	Sterile
Sterile Surgical Head Covers, Sterile Surgical Shoe Covers	Is	1	65414	Sterile
Sterile Single Use Eye Surgical Drape	Is	1	46697	Sterile
Sterile Single Use Surgical T.U.R Drape, Cystoscopy Drape and Percutaneous Nephrostomy Drape	Is	1	42559	Sterile
Sterile Single Use Urological Surgical Drape	Is	1	42559	Sterile
Sterile Single Use ENT Drape	Is	1	39230	Sterile