

Release date	24.12.2018	Revision	9
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MDD 93/42/EEC - 2007/47/EC DECLARATION OF CONFORMITY

Manufacturer Name: Eryiğit Endüstriyel Mak. ve Tıbbi Cih. İml. İth. İhr. İnş. Tic A.Ş.

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Product(s) : Steam Sterilizers, Low Temperature Gas H₂O₂ Gas Plasma Sterilizers,
Washer disinfectors, Oxygen production and storage systems

Classification : Steam Sterilization Device, H₂O₂ Gas Plasma Sterilizer, Washing and
Disinfection Equipment : Class IIb according to Annex IX, rule 15 of
the Medical Devices Directive / Oxygen and Nitrogen Production and
Storage System: Class IIb according to Annex IX, rule 11 of the
Medical Devices Directive

EC Certificate Number: 1984-MDD-10-013

We hereby declare that the products, as specified below in the attached list; Steam
Sterilizers, Low Temperature Hydrogen Peroxide Gas Plasma Sterilizers, Washer
Disinfectors, Oxygen and Nitrogen Production and Storage Systems are in accordance with
the directives of MDD 93/42/EEC Medical Devices amended by the Directive 2007/47/EC
Appendix II Article 3, starting from 26.12.2017.



Notified Body

Registration Number: 1984

Name : KIWA Belgelendirme Hizmetleri A.Ş.

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DIRECTIVES CE CLASSIFICATION OF DEVICES								
EC Directives	MDD 93/42/EEC Amended by the Directive 2007/47/EC - Annex.II Article.3 – Annex.IX, Rule 11 and 15, Class IIb							
Name or Identification of Medical Device and / or Accessory	Brand	Types	Model #	GMDN Code of Product	UNSPSC Code f Product	Class	Does The Medical device Sterile	
							Yes	No
Steam Sterilizer	ERYİĞİT	ERS STR	4407S, 4407V, 4410V, 4410S, 4410D, 5510S, 5510V, 5510D, 5512S, 5512V, 5512D, 6610S, 6610V, 6610D, 6613S, 6613V, 6613D, 7712S, 7712V, 7712D, 7715S, 7715V, 7715D, 7717S, 7717V, 7717D, 2000S, 2000V, 2000D 75, 75V	38671	42281508	IIb		X
		GOLDBERG	120S, 120V, 160S, 160V, 160D, 250S, 250V, 250D, 300S, 300V, 300D, 422S, 422V, 422D, 550S, 550V, 550D, 675S, 675V, 675D, 840S, 840V, 840D, 1000S, 1000V, 1000D, 2000S, 2000V, 2000D 75, 75V					
APPLIED STANDARDS			EN 60601-1, EN 60601-1-2, EN 62304, EN 285, EN 13445-1, EN 61010-40, EN 17665-1, EN 15223-1, EN14971					
Washer Disinfector	ERYİĞİT	TEKSTERİL	TSY 150, TSY 225, TSY 290M, TSY 2900, TSY 360, TSY 3000	35424	42281700	IIb		X
		GOLDBERG	GY 150, GY 225, GY 290M, GY 2900, GY 360, GY 3000					
APPLIED STANDARDS			EN60601-1, EN60601-1-2, EN62304, EN15883-1, EN15883-2, EN15883-3, EN15883-4, EN15883-5, EN15223-1, EN14971					
H ₂ O ₂ Peroxide Gas Plasma Sterilizer	ERYİĞİT	TEKSTERİL	TSP30, TSP 80, TSP 120, TSP 135, TSP 160, TSP 200	40567	42281508	IIb		X
		GOLDBERG	GP30, GP 80, GP 120, GP 135, GP 160, GP 200					
APPLIED STANDARDS			EN60601-1, EN60601-1-2, EN62304, EN 55011, EN 61010-40, EN15223-1, EN14971					

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Oxygen and Nitrogen Production and Storage Systems	ERYİĞİT	GOLDBERG	Oxy-Gold-2, Oxy-Gold-3, Oxy-Gold-4, Oxy-Gold-5, Oxy-Gold-7, Oxy-Gold-11, Oxy-Gold-15, Oxy-Gold-18, Oxy-Gold-22, Oxy-Gold-30, Oxy-Gold-37, Oxy-Gold-45, Oxy-Gold-55, Oxy-Gold-75, Oxy-Gold-90, Oxy-Gold-110 Oxy-Gold-132, Oxy-Gold-160, Oxy-Gold-200, Oxy-Gold-250, Oxy- Gold – Poliklinik-10, Oxy- Gold-Ambulans-10, Oxy- Gold-K-4, Oxy- Gold-K-5, Oxy- Gold-K-7, Oxy- Gold-K-11, Oxy- Gold-K-15, Oxy- Gold-K-18, Oxy- Gold-K-22, Oxy- Gold-K-30, Oxy- Gold-K-37, Oxy- Gold-M-10, Oxy- Gold-M-20, Oxy- Gold-M-30, Oxy- Gold-M-40	12873	42191603	Iib		X
APPLIED STANDARDS			EN60601-1, EN60601-1-6, EN62366, EN1041, EN14971, EN1012-1, EN286-1, EN7396-1, EN5359, EN11197, EN 15001					

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