

AORT	EC DECLARATION OF CONFORMITY				DI.01.01
Release Date	13.02.2015	Revision No.	08	Revision Date	12.02.2024

MANUFACTURER : AORT SAĞLIK HİZMETLERİ VE BİLGİ İŞLEM SİSTEMLERİ TURİZM
İNŞAAT SAN. TİC. LTD.ŞTİ

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Company Representative : DR. KENAN TEKİNDAG (General Manager)

Classification : MDD 93/42/EEC Medical Device Directive- ANNEX IX, Rule 15, Class IIB

Conformity Assessment : Full Quality Assurance System, Medical Device Regulation
93/42/EC - ANNEX II, (with exemption from Chapter 4)

Product Name : FULL AUTOMATIC ENDOSCOPE WASHER AND DISINFECTOR

PRODUCT NAME	MODEL	GMDN CODE	GMDN
Fully Automatic Endoscope Washer and Disinfector	APPENDIX-1 Table of Product Models	35012	<i>Disinfection Unit, Liquid Endoscope</i>

We declare that the attached product list meet the provisions of the council the medical device directive 93/42/EC. All supporting documents are retained under the premises of the manufacturer.

AORT SAĞLIK HİZMETLERİ
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Sarıgazi V.D. 12/02/24

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Related Harmonized Standards		
EN ISO 13485:2016/A11:2021	EN ISO 15883-1:2009/A1:2014	EN 60601-1-8:2007/A2:2021
EN 15223-1:2021	EN ISO 15883-4:2018	EN 61010-1:2010/A1:2019/AC:2019-04
EN ISO 20417:2021	EN ISO 15883-5:2021	EN 62366-1: 2015/A1:2020
EN 14971:2019/A11:2021	EN 61010-2-040:2021	EN 61326-1:2021
		EN 62304: 2006/A1:2015

NOTIFIED BODY

: KIWA BELGELENDİRME HİZMETLERİ A.Ş

NOTIFIED BODY ADDRESS: İstanbul Tuzla Organize Sanayi Bölgesi
Tepeören Mevkii 34957 Tuzla-İstanbul Türkiye**NOTIFIED BODY NO**

: 1984

CE CERTIFICATE PUBLICATION DATE

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CE CERTIFICATE VALIDITY DATE

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SIGNATURE

: General Manager/ Dr KENAN TEKİNDAG

AORT SAĞLIK HİZMETLERİ
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Sarıgazi V.D. İstanbul 11/24

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Product, Brand / Model and GMDN codes Table
endoCleaner endoscope Washer and Disinfection Unit / 35012

MODEL	Block Orfis Diameter	Air Valve Orifice Diameter	Amount of Air Passing Through the Channel
EC-111	7 mm	1.0 mm	1,5 L/5 sn
EC-112	7 mm	1.5 mm	1,5 L/5 sn
EC-122	7 mm	1.8 mm	1.5 L/5 sn
EC-211	8 mm	1.0 mm	1,5 L/5 sn
EC-212	8 mm	1.5 mm	1,5 L/5 sn
EC-222	8 mm	1.8 mm	1,5 L/5 sn
EC-311	9 mm	1.0 mm	2,0 L/5 sn
EC-312	9 mm	1.5 mm	2,0 L/5 sn
EC-322	9 mm	1.8 mm	2,0 L/5 sn
EC-411	10 mm	1.0 mm	2,0 L/5 sn
EC-412	10 mm	1.5 mm	2,0 L/5 sn
EC-422	10 mm	1.8 mm	2,0 L/5 sn
EC-511	9 mm	1.0 mm	2,2 L/5 sn
EC-512	9 mm	1.5 mm	2,2 L/5 sn
EC-522	9 mm	1.8 mm	2,2 L/5 sn
EC-611	10 mm	1.0 mm	2,2 L/5 sn
EC-612	10 mm	1.5 mm	2,2 L/5 sn
EC-622	10 mm	1.8 mm	2,2 L/5 sn
EC-711	7 mm	2.0 mm	1,5 L/5 sn
EC-712	8 mm	2.0 mm	2,0 L/5 sn
EC-722	9 mm	2.0 mm	2,2 L/5 sn
EC-811	8 mm	2.0 mm	1,5 L/5 sn
EC-812	9 mm	2.0 mm	2,0 L/5 sn
EC-822	10 mm	2.0 mm	2,2 L/5 sn
EC-911	8 mm	1.5 mm	2,5 L/5 sn
EC-912	9 mm	1.8 mm	2,5 L/5 sn
EC-922	10 mm	2.0 mm	2,5 L/5 sn

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