

Catalogue No. ARI-001

June 02, 2018





1- ABOUT UMB

1.1. Corporate

UMB Ltd. was established at 2011 in Turkey as a project office, now it is rendering to service engineering and manufacturing facilities to the medical waste management sector. It designs, manufactures, and supplies automated solutions for medical waste management. To reach the best quality in production, international standards of ISO-13485 in quality management system has been adopted recently and manufacturing is made in accordance with 97/23/EEC pressurized equipment directives and EN-285 the sterilization. Now, UMB proudly manufactures not only for Turkey but also for other countries worldwide with a %95 sales of its production to foreign markets.

1.2. Mission

UMB aims to improve the health and quality of life in the society and to develop and manufacture the most practical high-quality engineering solutions within technological advancement that will meet or exceed customer's needs and expectations. To achieve this; supplies medical waste treatment machines that have sterilization performance validation according to EN-285 and with lowest energy consumption to the industry.

1.3. Vision

To follow and create the latest technology in sterilization and shredding, and to utilize it in manufacturing high quality products. No concession from the ethics and principles of the science and conscience, providing reliable and quality service. To be an innovator for the scientific research and development as well as the new applications. To provide the best price for the best quality products.



2- ARI MEDICAL WASTE TREATMENT SYTEM

2.1. Design Criteria and Features of ARI

Product Description

ARI series systems are an integrated; shredder, solid & liquid medical waste sterilizer, drying unit and steam generator designed for treatment of medical waste.

Size reduction and sterilization of the medical waste carried out inside the waste vessel (WV). The WV is fitted with a motor-driven gearbox, with powerful shredding blades which can rotate in two directions to reduce the size and volume of the waste. Saturated steam supply to WV for sterilizing is generated in a steam generator that has capacity of 150 kg/hour for ARI-1100. The WV is designed and certified as a Large Steam Sterilizer in accordance with EN-13445.



Picture.1 Chisinau medical waste treatment plant equipped with ARI-550 system.

ARI is the most innovative model in the field of "medical waste disposal" and has been designed by using only the best features of the well accepted sterilizers in the market. ARI-550 design absolutely ensures that hot steam at ideal sterilization conditions of temperature and pressure, contacts entirely with shredded and cut waste materials during the sterilization cycle. Attach.4: Sterilization performance test results according to UN standards.



Pre-shredder: two-shaft shredder is integrated in the pressurized vessel to achieve guaranteed and homogeneous sterilization



Picture.2 and 3. ARI-1100 system installed to Timisoara Medical waste sterilization plant

All in one body design: Hopper, sterilization vessel and shredder are all in the same body without any external connections as bolt, screw, flange, etc. This design concept ensures safety, easiness and economy in operation.

Steps in a treatment cycle of ARI series medical waste systems:

a) First step in the treatment cycle is the transfer of the unsterilized medical waste with specially designed elevator for standard euro type waste containers into the shredder hopper. After this process the doors are closed, namely the contact between the waste and atmosphere prevented.
b) Secondly, shredder starts to operation and a proper vacuum is applied to remove the air bubbles so that steam can penetrate deep in the inner volumes of the waste material before the steam is fed into the vessel.

c) The steam jacket at the bottom side of the vessel, maintains the temperature of the walls at 134 °C, so the liquid under the vessel is heated homogeneously for liquid waste sterilization.
 d) Then hot steam is sent to the sterilization section to achieve the ideal sterilization conditions of temperature and pressure. After having reached to the plato stage, sterilization conditions are hold and maintained for sufficient time.



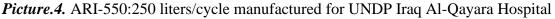
e) After sufficient time of exposure to steam, sterilization expires, and vacuum is applied to dry and cool down the sterile material and empty the steam inside through the vacuum pump.

f) Then air is fed into the vessel and atmospheric pressure is ensured after which the lid and the bottom door is opened automatically to empty the sterilize waste inside specially designed sterilization container.

Safety Features of ARI Medical Waste Systems

As autoclaves being critical equipment in terms of safety concerns and manufacturing based on standards, UMB's medical waste systems safety is guaranteed by the following:





- The material used is special material which is allowed to use in pressure vessel equipments.
- The safety switches used at the door system showing the door as open/closed and locked Advanced PLC control system allowing to limit maximum and minimum pressure values through PLC
- Mechanical base spring adjusted over pressure valve system
- Manufacturing based on 2014/68/EU Pressure Equipment Directives (PED) or ASME or GOST-R standards
- Manufacturing based on 98/37/EC Machinery Safety Regulation
- Manufacturing based on CE (Europe), ASME (North America), GOST-R (Russia) standards (See attached copies of the certifications)



- Certified autoclaves by world well-known certification agencies such as Bureau Veritas, TUV, and Hartford Steam Boilers etc.
- 10 year safety guarantee as part of CE



Picture.5.and 6. Outer shredder type manufactured for REMONDIS Gmbh. And some shredders





	Technical Spe	ecifications of ARI Series MV	VS Machines
Model	ARI-550:550 liters/cycle	ARI-550:250 liters/cycle	ARI-1100
1. Treatment method	Pre-shredder Type, Pressurized Steam Sterilization	Pre-shredder Type, Pressurized Steam Sterilization	Pre-shredder Type, Pressurized Steam Sterilization
2. Average Treatment Capacity	125 kg/h	60 kg/hour	250 kg / h
3. Feed Hopper Volume	550 liters	300 liters	1100 liters
4. Shredded Waste Part of Sterilization Vessel Volume	290 liters	290 liters	750 liters
5. Waste Feed System	Automatic, Elevator	Manual	Automatic, Elevator,
6. Shredder Type and Power	2 shafts, 15 Kw	2 shafts, 15 Kw	2-shafts, 18.5 kW
7. Feed & Discharge Lid Systems	Fully Automatic, With 3 Kw Vacuum Motor	Fully Automatic, With 2.2 Kw Vacuum Motor	Fully Automatic, With 4 Kw Vacuum Motor
8. Supporting Lock System for Feed & Discharge Lids	Pneumatic, 3-pistons, Fully Automatic		Pneumatic, 3-pistons, Fully Automatic
9. Duration of One Cycle	28-33 minutes	26-32 minutes	29-34 minutes
10. Sterilization Temperature	135-142 °C	135-142 °C	135-142 ºC
11. PLC, Automation System & Software	Schneider, Siemens, UMB	Schneider, Siemens, UMB	Schneider, Siemens, UMB
12. Steam Generator Capacity (electrical)	100 kg/h	80 kg/hour	150 kg / h
13. Water Supply Connection	1″	1″	1"
14. Water Consumption (average)	25 Liters/h	17 Liters/h	50 Liters / h
15. Power Connection	380 V, 50 Hz, 3-phase	380 V, 50 Hz, 3-phase	380 V, 50 Hz, 3-phase
16. Connected Power (including steam generator)	95 kW	80 kw	130 kW
17. Weight	3900 kg	3200 kg	5500 kg
18. Drying of Sterilized Waste	vacuum motor	Vacuum mechanism with 2.2 kw vacuum motor	vacuum motor
19. Sterile Waste Discharge	Automatically from the bottom door	Automatically from the bottom door	Automatically from the bottom door



2.3. Main Components of ARI Medical Waste Treatment Systems

a) Stainless steel sterilization chamber with various liters of waste capacity per cycle, in which size depends on the machine type; The material is AISI-316L with a thickness of 8-10 mm. It is tested and certified by TUV for CE certificate according to pressurized equipment directive (97/23/EC).

b) 125 or 150 kg/hour capacity steam generator; it also includes condense tank, pumping unit, and water purification unit,

c) Vacuum mechanism,

d) High and low-pressure management devices; Pressure sensors, safety switches, electromechanical pressure switches, and temperature sensors for sterilization chamber, and steam generator, **e**) PLC (Schneider) control unit, PLC program (UMB), 10-inch LCD touch screen display (Schneider).

f) Pneumatic pistons (6 for doors actuation), Top and bottom door has a clamp system, which 3 pistons used for actuation. On the other hand, bottom door has an extra inner door which actuated by a piston.

g) Shredder mechanism; motor with gearbox frequency converter, heat treated, and surface hardened AISI-4140 shredder knifes, gears and shafts,

- **h**) Elevator for waste transfer, (500 kg capacity, suited for 240, 440, 550, 770, and 1100 liters standard container)
- i) and subcomponents of these.

COMPRESSOR

- Brand: One of the Turkish Brand: according to country rules
- CE certificated, oil injection, air drying system,
- Capacity: 0,2 0,3 m3/min, 10 bar
- Dryer, filter and air tank (500 lt) are included
- Piping is included between autoclave and compressor

DOCUMENTATION TO BE PROVIDED

UMB is responsible to provide the following documents:

- Basic user manual and maintenance technical document in English
- Quality documents and pressure vessel test results
- Sterilization validation report
- Layout and assembly drawings for loads and civil works
- CE Certification

Warranty: Two years warranty against manufacturing and material failures. The shredder cutters (consumable parts) has 12 months under warranty or 2.000 hrs. Machine working time. The warranty period starts after the installation and start up or 60 days after the invoice date (whichever comes first). The worn-out parts and consumables are not subject to warranty.



AUTHORIZED INSTALLATION AND START UP SERVICE

- UMB will send detailed layout information to the customer prior to installation and start-up. The layout will clearly show the responsibilities of the customer and the preparations to be made at the plant where the commissioning and start-up will take place.
- The customer is responsible for unloading, and protection/safety of the equipment upon its arrival as well as arrangements of necessary crane, forklift and other lifting tools at his own expense.
- As per the layout, the required preparation needs to be made at the plant by the customer prior to installation. A written document will be signed by the customer for confirmation before UMB's technical team travel to the customer's plant. The preparations might include the required connections of power, steam, air etc.
- A team of **3** people will carry out installation at the customer's plant. The completion of physical assembly will be presented by the signed Technical Service Document. Approximate duration for installation is **10-15** days.
- Installation will only include connecting power cabling, general alignments, adjustment of valves and pipes, electrical connections from control unit to autoclave and provide training. A small amount of medical waste will be sterilized during start-up stage.
- At the training session, UMB will provide training to operators of the system and attend the real tests and initial process. The necessary commissioning service documentation will be prepared, and the customer will be requested to sign the service documents at the end.
- For installation and start-up, the customer is responsible for flight, accommodation, food expenses and transfers of the UMB Team during their stay at customer's own expense. For accommodation, an average hotel accommodation including food arrangements should be offered by the customer at its own expense
- Up on the arrival of UMB's team to the customer's country, the customer is responsible for the all of the transfers between airport, hotel, factory etc.
- It is important that the customer's qualified staff should be assigned during the UMB's team work to learn the system and gain training to operate the machines.
- During start-up, all of the necessary test materials/tools should be ready and prepared by the customer at the customer's own expense.
- In case if the commissioning and start-up are delayed due to the customer and extra training is required by the customer,
- The technical service document will be prepared and signed at the end of the service work.





8. Conclusion

According to the results of the testings performed it can be confirmed, that the Medical waste sterilization system container, SRN:ARI-550.004 manufactured by UMB Mühendislik passed all microbiological and thermo-electrical tests with biological indicators (10⁹) and is in conformity to the German standard DIN 58949-3 as well as the requirements of German RKI Guideline for Waste and also of STAATT Level IV (Inactivation of vegetative bacteria, fungi and lipophilic/hydrophilic viruses, parasites, mycobacteria and of *B. stearothermophilus* spores at 6 log₁₀ reduction or greater).

Archiving:

A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.

Reference:

The test results refer exclusively to the mentioned test piece. Extractions of this report only with a written permission of the HygCen Austria GmbH.

Prof. Dr. med. H.-P. Werner Technical Manager Inspector

Inspection report BI 22111



CERTIFICAT	
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5 •	Certificate
CERTIFICADO	Konformität mit der Bauart (Modul C1) nach Richtlinie 97/23/EG Conformity to Type (Module C1) according to Directive 97/23/EC
ERTIE	Zertifikat-Nr.: Z-IS-TGK-IST-14-11-5010281905-004-14-B-01236 Certificate No.:
•	Name und Anschrift : UMB MÜHENDISLIK PROJE MAKINA INŞ. des Herstellers: ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN. İÇ VE DIŞ TİC. LTD. ŞTİ.
CEPTN DNKAT	Name and postal adress of manufacturer: Vogsan 1472.Sok. No:72 OSTIM ANKARA/TURKEY Der Hersteller ist nach Prüfung der Voraussetzungen berechtigt, für die von ihm im Rahmen des Geltungsbereichs hergestellten Druckgeräte die CE-Kennzeichnung mit unserer Kennummer wie abgebildet zu verwenden: The manufacturer is - after examination of the prerequisites - authorized to provide his pressure equipment manufacturer within the scope of the examination with the CE-Mark and our identification number as illustrated: CE0036
•	Prüfbericht Nr.: P-IS-TGK-IST-14-11-5010281905-004-14-B-01236
턂t 타 봅	Test report No.: Geltungsbereich: 550 Lt Sterilization chamber with 2,2 Bar PS and 4 Bar PT Scope of examination: Seri No: ARI-550. 001A
25	Fertigungsstätte: OSTIM ANKARA / TURKEY Manufacturing plant:
•	TÜV SED Industrie Service GmbH
ERTIFICATE	Istanbul 21.11.2014 (Ort, Datum) (Place, Date) HAKIM OZLUK Benamić Stelle, Kegnummer 0036 Notified body No: 0036
•	
zertifikat • certificat	TÜV SÜD Türkiye - Büyükdere Cəddesi - No.103/A - Sarlı 1ş Merkezi - A Blok Kat.5 34394 Mecidiyeküy - İstanbul - Türkiye
	TUV SUD Türkiye - Büyükdere Cəddesi - No. 103/A - Şarlı 1ş Merkezi - A Blok Kat. 5 34394 Mecidiyeköy - İstanbul - Türkiye

ALCONG.



CePtn@nkat + Certificado + Certificat Turkiye ZERTIFIKAT Certificate EG-Baumusterprüfung (Modul B) nach Richtlinie 97/23/EG EC Type-examination (Module B) according to Directive 97/23/EC Zertifikat-Nr.: Z-IS-TGK-IST-14-11-5010281905-002-14-B-01236 Certificate No.: UMB MÜHENDİSLİK PROJE MAKİNA İNŞ. Name und Anschrift Name and postal address of manufacturer: CEVRE VE TIBBİ CİHAZLAR İMALAT SAN. IC VE DIS TIC. LTD. STL İvogsan 1472, Sok. No:72 OSTİM ANKARA/TURKEY Hiermit wird bescheinigt, dass der unten genannte Entwurf die Anforderungen der Richtlinie 97/23/EG erfüllt. We herewith certify that the type mentioned below meets the requirements of the Directive 97/23. Prüfbericht Nr.: P-IS-TGK-IST-14-11-5010281905-002-14-B-01236 Test report No .. Geltungsbereich: 550 Lt Sterilization chamber with 2,2 Bar PS and 4 Bar PT Drawing No: Sterilization Chamber Rev.1 Scope of examination: Approved by TÜV SÜD Designer at date 21.11.2014 詰 İvogsan 1472. Sok. No:72 OSTİM Fertigungsstätte: 븗 ANKARA/ TURKEY Manufacturing plant Re sun industrie CERTIFICATE TEV SUD Guthstrie Service GmbH TEV SUP Gruppe TUV-CRRCZertifizierungsstelle Istanbul, 21.11.2014 (Ort, Datum) für Druckgeräte (Hakim ÖZLÜK) Stelle, Kennummer 0036 ZERTIFIKAT

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TÜV SÜD Türkiye - Büyükdere Caddesi - No.103/A - Şarlı İş Merkezi - A Blok Kat, 5 34394 Mecidiyeköy - İstanbul - Türkiye

TUV®





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Türkiye

	TEST REPORT
	IEC/EN 60204-1
	nery - Electrical equipment of machines GENERAL REQUIREMENTS
Project No:	14-B-01236-01
Date of issue:	15/12/2012
Testing laboratory	UMB MÜHENDİSLİK PROJE MAKİNA İNŞ. ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN. İÇ VE DIŞ TİC. LTD.ŞTİ.
Address:	ÍVOGSAN 1472. Sok. No: 72 OSTÍM ANKARA TURKEY
Testing location:	as above
Applicant:	UMB MÜHENDİSLİK PROJE MAKİNA İNŞ. ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN. İÇ VE DIŞ TİC. LTD.ŞTİ.
Address:	İVOGSAN 1472. Sok. No: 72 OSTİM ANKARA TURKEY
Standard	IEC 60024-1. Ed. 5 : 2005 / EN 60204-1:2006 /AC:2010
Test Report Form No	IEC/EN 60204-1_K03-E03-CL008 Rev.00
Test procedure:	방향 : : : : : : : : : : : : : : : : : : :
Procedure deviation:	
Non-standard test method	
National deviations:	
Number of pages (Report)	15
Number of pages (Attachments):	- (iiŤv)
Compiled by: Mutu DEMIR	Approved by: M.Koray EFE , /
(+ signature) Muthorewick	(+ signature)
ρ^{*}	1100





ÜZEN NORWEST

CEVRE, GIDA VE VETERİNER SAĞLIK HİZMETLERİ EĞİTİM DANIŞMANLIK TİCARET A.Ş. Büyükesat Mn. Kaptanpaşa Sk. No: 2 06700 G.O.P. • ANKARA Tel: 0312, 447 29 99 Faks: 0312, 447 86 66 • www.duzennorwest.com.tr

EVALUATION REPORT

Customer Name	: UMB MÜH.PRO. MAK.İNŞ, ÇEVRE VE TIBBİ CİHAZLAR İMAL.SAN.LTD.ŞTİ
Customer Address	: İVOKSAN 1472. CADDE, NO:72 YENİMAHALLE/ANKARA
Tel / Fax	: (0312) 395 08 14 / (0312) 395 18 09
ArrivalDate	: 09.12.2014
Analysis Date	: 09.12.2014
Report Date	: 12.12.2014
Sample Information	:Bioindicators (4 Processed&1 UnprocessedBioindicator) which were provided by the Düzen Norwest Laboratory (Merck Sterikon © plus branded, LOT: VM 570874 408, Exp.Date: 04.08.2014 was taken to the laboratory with thermal protection, and arrived at 15:27.By the customer request, sample was analysed as private request.
	Detailed information of the bioindicators which used in the analysis is achievable at http://www.merckmillipore.com/TR/tr/product/Sterikon%C2%AE-plus-Bioindicator,MDA_CHEM- 110274#anchor_MSD
Explanation	: This is the English version of the evaluation report of the samples coded as DÇ-10416, DÇ-10417, DÇ- 10418, DÇ-10419 ve DÇ-10420. For each sample analysis report is provided in the annex.

By the customer request, ARI-550 branded instrument with 0001 serial number, and worked under supervision of Düzen Norwest staff. Bioindicator which was provided by the Düzen Norwest Laboratory was put into the instrument which was programmed to work 15minutes at 134°C and under 2,2 bars pressure, was worked for 34 minutes under supervision of Düzen Norwest staff. Bioindicators was placed as specified in the annex-1.

Processed Bioindicators and Unprocessed Bioindicator was incubated for 24-48 hours at 60°C and change in the color has been checked. It is stated that, yellow color seen in the bioindicator after incubation shows inefficient sterilisation where purple color shows efficient sterilisation.

REGISTER NUMBER	SAMPLE NAME	ANALYSIS RESULTS
DÇ-10416	Processed Bioindicator Number 1	Purple
DÇ-10417	Processed Bioindicator Number 2	Purple
DÇ-10418	Processed Bioindicator Number 3	Purple
DÇ-10419	Processed Bioindicator Number 4	Purple
DC-10420	Unprocessed Bioindicator	Yellow

MicrobiologyLab.

Gülcan AYDIN

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Executive and Technical Manager **GÜLVEREN TASKIN** AGRIVEST CEVRE GIDA **NUZEN** FTER ER S

12727818 and

ANNEARA 323 447 86 68 323 913 85 17

Thisreportconsists of 2pages.

KYF 510-1



PCA PARTNERS CERTIFICATE ASSURANCE





ISO 9001 : 2008

UMB MÜHENDİSLİK PROJE MAKİNA İNŞAAT ÇEVRE VE TIBBİ CİHAZLAR İMALAT SANAYİ İÇ VE DIŞ TİCARET LTD. ŞTİ.

İstasyon Mah. Talat Paşa Cad. 47/14C 4 Merkez Edirne/ TURKEY

This certificate shows that the quality management system of the above company was approved by PCA Sertifikasyon for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria.

SCOPE

Design and manufacture of medical waste sterilization systems, industrial milling, welded fabrication and machining

Certificate No Registration Date Reissue Date Expiry Date Certificate Period

: : 08.05.2018 : 3 Years (From the date of registration)

: KY-23048

:09.05.2017

PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / ISTANBUL Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49 www.pca-tr.com info@pca-tr.com



Management Systems Certification Body MSCB-103

FR.86 Rev.2



PCA PARTNERS CERTIFICATE ASSURANCE





ISO 14001 : 2004

UMB MÜHENDİSLİK PROJE MAKİNA İNŞAAT ÇEVRE VE TIBBİ CİHAZLAR İMALAT SANAYİ İÇ VE DIŞ TİCARET LTD. ŞTİ.

İstasyon Mah. Talat Paşa Cad. 47/14C 4 Merkez Edirne/ TURKEY This certificate shows that the environmental management system of the above company was approved by PCA Sertifikasyon for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria.

SCOPE

Design and manufacture of medical waste sterilization systems, industrial milling, welded fabrication and machining

Certificate No Registration Date Reissue Date Expiry Date Certificate Period

: CY-31323 : 09.05.2017 : : 08.05.2018 : 3 Years (From the date of registration)



ACCREDITED Management Systems Certification Body MSCB-103

Quad

PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49 www.pca-tr.com info@pca-tr.com

FR.86 Rev.2

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OHSAS 18001 : 2007

UMB MÜHENDİSLİK PROJE MAKİNA İNŞAAT ÇEVRE VE TIBBİ CİHAZLAR İMALAT SANAYİ İÇ VE DIŞ TİCARET LTD. ŞTİ.

İstasyon Mah. Talat Paşa Cad. 47/14C 4 Merkez Edirne/ TURKEY

This certificate shows that the occupational health and safety management system of the above company was approved by PCA Sertifikasyon for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria.

SCOPE

Design and manufacture of medical waste sterilization systems, industrial milling, welded fabrication and machining

- Certificate No **Registration Date Reissue Date** Expiry Date **Certificate Period**
- : 09.05.2017 . :08.05.2018 : 3 Years (From the date of registration)

: OH-51190



PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49 www.pca-tr.com info@pca-tr.com

FR.86 Rev.2