



*LARGE CAPACITY  
PHARMACEUTICAL  
AUTOCLAVES*

 **eryiğit**



## Our Vision

Our vision is to make Eryiđit an example among its class on its way to become the first medical device manufacturer that comes to mind internationally.

## Our Mission

Our mission is to enhance the value that we give to environment, society, customers and company staff continuously with honesty and efficiency.





## CUTTING-EDGE TECHNOLOGY

## FOR LIFE

### Environment and Quality Policy

Since its establishment in 1991, the company offers high quality, advanced technology and reasonable price. Always committed to leave a cleaner environment for the future and to take responsibility for the community has become the main goal of our company.

Eryigit always adopts "Quality" as a goal, guarantees that its products are produced at the highest international standards in order to meet the continuous demands and expectations and to ensure customer satisfaction.

Eryigit's production is entitled with GMP certificate by establishing the requirements for good manufacturing practices.

As Turkey's leading medical device manufacturer, Eryigit Medical Devices has been proudly serving the healthcare industry for 26 years..

Our company holds **ISO 9001** and **ISO 13485** Quality Management Systems and holds as well the environmental awareness and compliance with legal regulations, being also certified with **ISO 14001** Environment Management System. Furthermore, our company is certified with **CE1984 for Medical Devices Directive** and **CE1783 for the Pressure Equipment Directive**.

As a result of our work, our steam sterilizers have been crowned with a Medical Test certificate, which we have received after the tests conducted by the German accredited company HYGCEN.

The validation tests have been successfully applied to our steam sterilizers according to **TS EN 17665-1** by **HYGCEN** and they continue to be applied. Eryigit Medical Devices Inc., located in Ankara, Ostim Ivedik O.S.B and its 10.000 m2 factory, are built with strong and valuable human capital ensuring that its production continues among the leading institutions of the domestic and international health sector, industry and research and development.



# “We Produce in Turkey. Sell to the World...”

## More than 50 countries around the World

### 1500 Hospitals in 81 cities in Turkey



**eryiğit**

[www.eryigit.com.tr](http://www.eryigit.com.tr)



TS EN 285





# 2000 Lt LARGE CAPACITY AUTOCLAVE

**Pharmaceutical Autoclave**



The type test and validation services of our products are carried out by Hygcen GmbH, the German accredited organization.

# Large Capacity Pharmaceutical Sterilizer

## Technical Features

Chamber Dimensions		Generator Technical Features
<b>MODEL STR 2000</b>		<b>MODEL STR 2000</b>
Chamber Volume (lt)	2000	Generator Power (3 Phase/400 ± 100 VAC)
Diameter (mm)	-	Installation Power ( kW ) 70
Width (mm)	1100	Generator Volume (lt) 90
Height (mm)	1230	
Depth (mm)	1450	

External Dimensions		Weight
<b>MODEL STR 2000</b>		<b>MODEL STR 2000</b>
Width (mm)	2786	Device (kg) 2800
Height (mm)	2025	Package (kg) 3200
Depth (mm)	1830	

Package Dimensions		Chamber Capacity
<b>MODEL STR 2000</b>		<b>MODEL STR 2000</b>
Width (mm)	2950	Chamber Volume (lt) 2000
Height (mm)	2190	STU Capacity (lt) 24
Depth (mm)	2030	

Medical Device Directive	: MDD 93/42/EEC, 2007/47/EC
Medical Device Type	: IIb, EC MDD 93/42/EEC 2007/47/EC
Low Voltage Directive	: 2006/95/EC - EN 60601-2-040
Electromagnetic Compatibility Directive	: 2004/108/EC EN 60601-1-2
Pressure Vessels Directive	: PED 97/23/EC : EN 13445-1, -2, -3, -4, -5
High Capacity Sterilizer Directive	: TSEN285:2006 + A2:2011
Quality Management System Requirements	: ISO 9001
Quality Management Systems Requirements – Medical Devices	: ISO 13485
Environment Management Systems – Requirements for Manual User	: ISO 14001
Good Manufacture Practices	: GMP

Glass Bottles (121°C)	: ~ 105 min.
Irrigation Plastics (121°C)	: ~ 105 min.
Parenteral Plastics (121°C)	: ~ 105 min.
Bowie - Dick Test (134°C)	: ~ 45 min.
Vacuum Leakage Test	: ~ 25 min.
Number of Programs	: 10



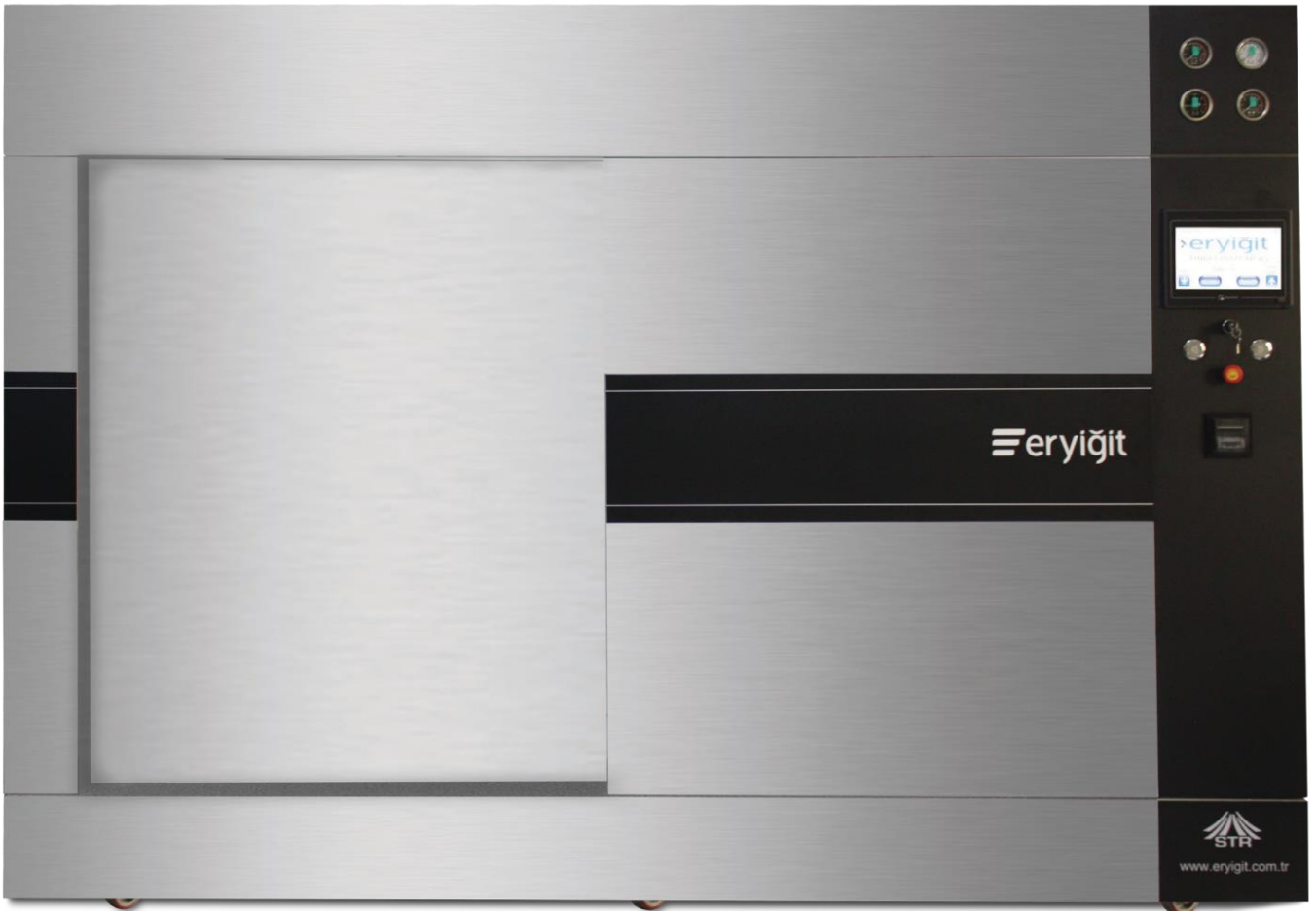
## High Quality Standards

ERYİĞİT complies with all sterilizers, Medical Device Directive 93/42 / EEC, Pressure Vessel Directive 97/23 / EEC, 2006/95 / EC Low Voltage Directive, 2004/108 / EC Electromagnetic Compatibility Directive, 2011/65 / EC RoHS Directive 2006/42 / EC Machine Safety Directive, such as the EN285 Steam Sterilizer standard, is manufactured in strict compliance with the most stringent and detailed world quality and service standards.

## Large Capacity Autoclave of Pharmaceutical

Produced with superior technology and high performance, our products always follow the needs of our customers.

It can be produced as 1000 lt, 2000 lt.



- ✓ The surface panels of the autoclave are made of AISI 304 quality stainless steel material.
- ✓ The autoclave has a microprocessor control that is programmable.
- ✓ When the autoclave is requested, it is capable of being fed either from the central steam system or from the internal generator system.
- ✓ 10 " touch LCD screen.
- ✓ There is a turbo fan ventilation system which ensures that materials are cooled after sterilization and the materials are dried out after the process.
- ✓ AISI 316L quality stainless steel material heat exchanger is available.
- ✓ The autoclave boiler is manufactured from AISI 316 quality stainless steel according to PED 97/23 / EEC directive.
- ✓ Drainage system for wastewater is available.
- ✓ The autoclave door is sliding door and has a sensor security system.
- ✓ The Hepa filter, which holds 99.998% of particles larger than 0.3 µm in diameter, is present in the air entering the chamber.
- ✓ The autoclave has one validation port, one boiler, one glass bottle temperature sensor and one boiler pressure sensor.
- ✓ Autoclave's temperature sensor is of type PT100 and its accuracy is  $\pm 0,1$  ° C.
- ✓ The pipe on the autoclave is made of AISI 304 quality stainless steel material.
- ✓ Hot water and steam pipes are insulated with vinyl covered cellulose foam.
- ✓ A built-in printer is available.
- ✓ USB or RS232 or RS485 input is available in autoclave.





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# Our Certificates

**TÜRK STANDARLARI ENSTİTÜSÜ**  
**CERTIFICATE OF FULL QUALITY ASSURANCE MODULE**  
 (INCLUDING DESIGN EXAMINATION)

**ERYİĞİT ENDÜSTRİYEL MAK. VE TIBBİ CİH. İML. İTH. İNŞ. TİC. A.Ş.**

Notified at the address  
**İVEDİK ORG. SAN. ÖZANADOLU SAN. SİT. 1453. SOK. NO: 3 OSTİM ANKARA**  
 for the scope of:

"ERYİĞİT" trademark  
 750 l Sterilizer Volume, 7.5 KW Power Resistance,  
 750 l Sterilizer Volume, 7.5 KW Power Resistance,  
 150 l Sterilizer Volume, 20 KW Power Resistance, 60 l Generator Volume,  
 150 l Sterilizer Volume, 20 KW Power Resistance, 60 l Generator Volume,  
 250 l Sterilizer Volume, 30 KW Power Resistance, 60 l Generator Volume,  
 250 l Sterilizer Volume, 30 KW Power Resistance, 60 l Generator Volume,  
 300 l Sterilizer Volume, 30 KW Power Resistance, 60 l Generator Volume,  
 400 l Sterilizer Volume, 40 KW Power Resistance, 70 l Generator Volume,  
 400 l Sterilizer Volume, 40 KW Power Resistance, 70 l Generator Volume,  
 450 l Sterilizer Volume, 40 KW Power Resistance, 70 l Generator Volume,  
 450 l Sterilizer Volume, 40 KW Power Resistance, 70 l Generator Volume,  
 1000 l Sterilizer Volume, 20 KW Power Resistance, 50 l Generator Volume,  
 3 bars Operating Pressure, Steam Sterilizer Control (Cihazlar)

Have been examined and verified to the requirements of  
**97/23/EC – Pressure Equipment Directive**  
**Full Quality Assurance Module – Module H1 (Annex III)**  
 By considering the related clauses of TR EN ISO 9001:2008

Notified Body Number: 1783  
 Date of Issue: 08.05.2009  
 Valid Until: 08.05.2016  
 Examination Report Number: 222-PEC-020 / 2013 - 01  
 Date / Reason of the Certificate Revision: 06.05.2012 / Renewal of certificate

This certificate remarks that quality system meets requirements of the technical regulations / harmonized standards and with this certificate the company is authorized to affix CE Mark, as shown below, and Notified Body Number on the products. In the scope of the examined quality system, notified body has the right to carry out surveillance visits announced at annexed.

**CE** Certificate Number: 1783 - PED - 014

Notified Body  
**TÜRK PATENT ENSTİTÜSÜ**  
 The Product Certification Center  
 ANKARA Rev.01 08/05/2012

T.C.  
**TÜRK PATENT ENSTİTÜSÜ**

**FAYDALI MODEL BELGESİ**

No: TR 2014 06828 Y

*Bu Belge 551 Sayılı Patent Haklarının Korunması Hakkında Kanun Hükmünde Kararname'nin 162 nci maddesi uyarınca 12.06.2014 tarihinden itibaren 10 yıl süre ile verilmiştir.*

**Prof. Dr. Habip ASAN**  
Enstitü Başkanı

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**SERTİFİKA**  
 CERTIFICATE ॐॐॐ ZERTIFIKAT ॐॐॐ CERTIFICATO

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**ERYİĞİT ENDÜSTRİYEL**  
**MAKİNE VE TIBBİ CİHAZLAR İMALAT İTHALAT İHRACAT İNŞAAT TİCARET A.Ş.**

MEYER ORGANİZASYON SANAYİ BÖLGE 4633. SK. NO: 3 06370 OSTİM - ANKARA - TÜRKİYE

DESIGN, MANUFACTURE, SALES AND SERVICING OF CENTRAL STERILIZATION UNITS AND STEAM STERILIZERS, HYDROGEN PEROXIDE GAS PLASMA STERILIZER, LABORATORY TYPE PERPENDICULAR AUTOCLAVE, SURGICAL WASHING AND DISINFECTION DEVICES, SURGERY TABLES AND TRACTION RITS, SURGERY CEILING LAMPS, GYNECOLOGIC, UROLOGIC, DELIVERY AND EXAMINATION TABLES, HOSPITAL STERILIZATION STAINLESS EQUIPMENT AND ENT CHAIR

**ISO 13485:2003**  
 Medical devices - Quality management systems - Requirements for regulatory purposes

Initial Certification Date: 12 January 2008  
 Recertification Date: 18 January 2013  
 Expiration Date: 18 January 2016

**TÜRKİYE**

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**ISO 9001:2008**  
 Quality management systems - Requirements

Initial Certification Date: 12 January 2008  
 Recertification Date: 18 January 2013  
 Expiration Date: 18 January 2016

**TÜRKİYE**







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