



Türkiye

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.:

Name und Anschrift UMB MÜHENDİSLİK PROJE MAKİNA İNŞ.
Name and postal address of manufacturer: ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN.
İÇ VE DIŞ TİC. LTD. ŞTİ.
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
Scope of examination: Drawing No: Sterilization Chamber Rev.1
Approved by TÜV SÜD Designer at date 21.11.2014

Fertigungsstätte: İvogsan 1472. Sok. No:72 OSTİM
Manufacturing plant ANKARA/ TURKEY

Istanbul, 21.11.2014
(Ort, Datum)





Industrie Service

TÜV Süd TGK

Büyükdere Cad.Şarlı İş Merkezi, No:103/A, Kat:5 , TR-34394 Mecidiyeköy– İstanbul

Prüfbericht – Nr.: P- IS-TGK-IST-14-09-5010201197-003-14-B-01236

Technical File examination according to directive 97/23/EC

Auftraggeber: TÜV SÜD
Commissioned by: Büyükdere Cad. Şarlı İş Merkezi No:103/AKat:5
TR-34394 Mecidiyeköy- İstanbul
Hersteller: UMB MÜHENDİSLİK PROJE MAKİNA İNŞ.
Manufacturer: ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN.
İÇ VE DIŞ TİC. LTD. ŞTİ.
İvogsan 1472. Sok. No:72 OSTİM
ANKARA/TURKEY

Prüfobjekt: STERILIZATION CHAMBER
Test Item:

Prüfgrundlage: EN13445-3/ 97/23 EC
Basis of Examination:

Zeichnungs-Nr.: STERILIZATION CHAMBER Rev.1
Drawing No:

Auftrag Nr.: 14-B-01236
Commission No:

Auslegungsdaten:
Design Data:

max. zul. druck (PS) max.allowable pressure	bar	2,2
max. zul. Temp (TS) max.allowable temperature	C	20/135
Inhalt capacity	liter	550
Heizfläche heating surface	m2	N/A
zul. Dampferzeugung adm.steam quantity	kg/h	N/A
Prüfdruck (PT) test pressure	bar	4

Konformitäts- Modul B
bewertungsverfahren Fluidgruppe 2
Conformity assesment procedure

Anlagen STERILIZATION CHAMBER
annex technical file,

TÜV Süd Teknik Güvenlik ve Kalite Denetim Sanayi ve Ticaret Ltd.Şti.
TÜV SÜD Group

Telefon : (0212) 347 98 10 / pbx Telefax : (0212) 347 98 11

e-mail : info@tuv-tgk.com

Ticaret Sicili: 232461 / 180027



Industrie Service

TÜV Súd TGK

Büyükdere Cad.Şarlı İş Merkezi, No:103/A, Kat:5 , TR-34394 Mecidiyeköy– İstanbul

Dear Sirs,

According to your order, dated 21.11.2014, we have evaluated the document (type evaluation) in Module B of the pressure equipment directive 97/23/EC (PED). Result of our evaluation was:

- ... No special objections were found.
- ... Please observe our additional notes and our remarks in the drawing.
- ... A re-evaluation is not required.
- ... The particular material appraisal was based on the applied technical specification EN.
- ... Deviations, additions to or exclusions from the test specification: none
- ... Non-standart test methods or procedures utilised: none
- ... Utilised measurements, examinations and derived results: none

Additional notes:

- ... Design is based on EN 13445-3. All documentation and testing during final assesment should be inspected.
- ... Manufacturing records, test reports of first manufactured vessel should be included in technical file.
- ... Calculations of vessel should be included in technical file.
- ... Bolt and nut material should be according to EN 13445.
- ... No external loads are considered on calculations.
- ... No nozzle loads are considered on calculations.
- ... Those documents and information should be inspected in technical file:
 - Vessel handling-transportation-erection methode.
 - Erection site conditions (ambient temperature, wind, earthquake)
 - Lifting procedure
 - Safety valve set point-capacity and location.

TÜV Súd Teknik Güvenlik ve Kalite Denetim Sanayi ve Ticaret Ltd.Şti.

TÜV SÜD Group

Telefon : (0212) 347 98 10 / pbx Telefax : (0212) 347 98 11

e-mail : info@tuv-tgk.com

Ticaret Sicili: 232461 / 180027



Industrie Service

TÜV Súd TGK

Büyükdere Cad.Şarlı İş Merkezi, No:103/A, Kat:5 , TR-34394 Mecidiyeköy– İstanbul

... Those documentation should be inspected in vessel manufacturing file during final assesment:

- Welder certificates
- Welding procedure specifications
- Material certificates
- NDT personnel qualification,
- Material tracebility records,
- Dimension control records with tolerances

... If plates are flame-cut, grinding-machining should be applied

... If hydrostatic test is applied by pnomatic, a safety procedure should be applied

We keep one set of technical file for our documentation.

The invoice in connection with this evaluation will be send seperately.

The results of evaluation are valid only for the documents referred to hereunder. Reproduction of this report except a reproduction in full requires our written approval.

With best regards,

Tüv Súd Industrie Service

Hakim ÖZEL

Mutlu DEMİR

Benannte Stelle, Kennnummer 0036

Istanbul, 21.11.2014

Enclosure:

1 set of **Sterilization Chamber UMB MÜHENDİSLİK PROJE MAKİNA İNŞ. ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN. İÇ VE DIŞ TİC. LTD. ŞTİ.**

technical file.

TÜV Súd Teknik Güvenlik ve Kalite Denetim Sanayi ve Ticaret Ltd.Şti.

TÜV SÜD Group

Telefon : (0212) 347 98 10 / pbx Telefax : (0212) 347 98 11

e-mail : info@tuv-tgk.com

Ticaret Sicili: 232461 / 180027



ZERTIFIKAT Certificate

**Konformität mit der Bauart (Modul C1)
nach Richtlinie 97/23/EG**
Conformity to Type (Module C1) according to Directive 97/23/EC

Zertifikat-Nr.: Z-IS-TGK-IST-14-11-5010281905-004-14-B-01236
Certificate No.:

**Name und Anschrift
des Herstellers:**

**: UMB MÜHENDİSLİK PROJE MAKİNA İNŞ.
ÇEVRE VE TIBBİ CİHAZLAR İMALAT
SAN. İÇ VE DIŞ TİC. LTD. ŞTİ.**

Name and postal address of manufacturer: **İvogsan 1472.Sok. No:72 OSTİM 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 Kennnummer wie abgebildet zu verwenden:**

*The manufacturer is - after examination of the prerequisites - authorized to provide his pressure equipment
manufactured within the scope of the examination with the CE-Mark and our identification number as illustrated:*

CE 0036

Prüfbericht Nr.:
Test report No.:

P-IS-TGK-IST-14-11-5010281905-004-14-B-01236

Geltungsbereich:
Scope of examination:

**550 Lt Sterilization chamber with 2,2 Bar PS and 4 Bar PT
Seri No: ARI-550. 001A**

Fertigungsstätte:
Manufacturing plant:

OSTİM ANKARA / TURKEY

Istanbul 21.11.2014
(Ort, Datum)
(Place, Date)

**TÜV SÜD Industrie Service GmbH
TÜV SÜD Gruppe
TÜV-CERT Zertifizierungsstelle
für Druckgeräte
HAKİM OZLUK**

**Benannte Stelle, Kennnummer 0036
Notified body No: 0036**



Report regarding the performance of an unexpected visit



Industrie Service

Report-Nr.	P-IS-TGK-IST-14-11-5010281905-004-14-B-01236
Customer:	UMB MÜHENDİSLİK PROJE MAKİNA İNŞ. ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN. İÇ VE DIŞ TİC. LTD. ŞTİ.
Manufacturing plant:	İvogsan 1472. Sok. No:72 OSTİM ANKARA/TURKEY
Legal basis, module:	Directive ☐ 87/404/EEC; ☒ 97/23/EC; ☐ 1999/36/EC; Module B+C1
Certification contract dated:	31.10.2014
Certificate No.:	Z- IS-TGK-IST-11-05-1210001429-02-14 B 01236 for B Date: 21.11.2011
Range of approval:	Manufacturing Steam Generator and Sterilization chamber types ARI-550. 001B capacity from 70 L and 550 L , Steam generator have 3,2 Bar PS and Sterilization chamber have 2,2 PS
Agreed number of unexpected visits per year:	2 per year
Auditor / Inspector	HAKIM ÖZLÜK

1. Evaluation of administrative, organizational and technical prerequisites:

No	E	TE	NE	NZ		Appdx
1.	☒	☐	☐	☐	Manufacturing is performed according to the technical records.	☐
2.	☒	☐	☐	☐	EC-type examination and/or the certification are still valid	☐
3.	☒	☐	☐	☐	The approvals for operating procedures employed are still valid.	☐
4.	☒	☐	☐	☐	The approvals for joining personnel are still valid.	☐
5.	☒	☐	☐	☐	The approvals for NDT personnel are still valid.	☐
6.	☒	☐	☐	☐	The qualifications for other personnel are still valid.	☐
7.	☒	☐	☐	☐	There have been no changes in the application and the use of production methods and equipment.	☐
8.	☒	☐	☐	☐	Appropriate methods to ensure the traceability of materials are applied.	☐
9.	☒	☐	☐	☐	Initial inspections are performed according to Directive 1999/36 EC	☐
10.	☒	☐	☐	☐	Marking / labeling is performed according to Directive 1999/36/EC.	☐
11.	☒	☐	☐	☐	The operating manual is issued and given with the pressure equipment.	☐

E = satisfied; TE = partly satisfied (see attached sheet); NE = not satisfied (see attached sheet); NZ = not applicable

2. Checks:

☒	Checks on the pressure equipment were performed during the unexpected visit.
☒	The test reports have been handed out to the manufacturer.
☒	The manufacturer was obliged to communicate the production program planned so that the check during the unexpected visits can be performed.

TÜV Industrie Service GmbH · TÜV SÜD Group
Notified Body 0036 according to PED
Location: Istanbul, on 23.05.2011

Attachment: ☐ Appendix
Distributor: ☒ Manufacturer
☐ PED-QS-Certification body
☐ Document

For the test laboratory:

Local certifier:

Surname Name, organization unit

Özlük, Hakim

Surname Name, organization unit





ZERTIFIKAT Certificate

Konformität mit der Bauart (Modul C1)
nach Richtlinie 97/23/EG
Conformity to Type (Module C1) according to Directive 97/23/EC

Zertifikat-Nr.: Z-IS-TGK-IST-14-11-5010281905-003-14-B-01236
Certificate No.:

Name und Anschrift
des Herstellers: UMB MÜHENDİSLİK PROJE MAKİNA İNŞ.
ÇEVRE VE TIBBİ CİHAZLAR İMALAT
SAN. İÇ VE DIŞ TİC. LTD. ŞTİ.

Name and postal adress of manufacturer: İvogsan 1472.Sok. No:72 OSTİM 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 Kennnummer wie abgebildet zu verwenden:

The manufacturer is - after examination of the prerequisites - authorized to provide his pressure equipment
manufactured within the scope of the examination with the CE-Mark and our identification number as illustrated:

CE 0036

Prüfbericht Nr.: P-IS-TGK-IST-14-11-5010281905-003-14-B-01236
Test report No.:

Geltungsbereich: 70 Lt Steam Generator with 3,2 Bar PS and 5 Bar PT
Scope of examination: Seri No: ARI-550. 001B

Fertigungsstätte: OSTİM ANKARA / TURKEY
Manufacturing plant:

Istanbul 21.11.2014
(Ort, Datum)
(Place, Date)

TÜV SÜD Industrie Service GmbH
TÜV SÜD Gruppe
TUV-CERT-Zertifizierungsstelle
für Druckgeräte

HAKİM OZLUK

Benannte Stelle, Kennnummer 0036
Notified body No: 0036



Report regarding the performance of an unexpected visit



Industrie Service

Report-Nr.	P-IS-TGK-IST-14-11-5010281905-004-14-B-01236
Customer:	UMB MÜHENDİSLİK PROJE MAKİNA İNŞ. ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN. İÇ VE DIŞ TİC. LTD. ŞTİ.
Manufacturing plant:	İvogsan 1472. Sok. No:72 OSTİM ANKARA/TURKEY
Legal basis, module:	Directive ☐ 87/404/EEC; ☒ 97/23/EC; ☐ 1999/36/EC; Module B+C1
Certification contract dated:	31.10.2014
Certificate No.:	Z- IS-TGK-IST-11-05-1210001429-02-14 B 01236 for B Date: 21.11.2011
Range of approval:	Manufacturing Steam Generator and Sterilization chamber types; ARI-550. 001A capacity from 70 L and 550 L , Steam generator have 3,2 Bar PS and Sterilization chamber have 2,2 PS
Agreed number of unexpected visits per year:	2 per year
Auditor / Inspector	HAKIM ÖZLÜK

1. Evaluation of administrative, organizational and technical prerequisites:

No	E	TE	NE	NZ		Appdx
1.	☒	☐	☐	☐	Manufacturing is performed according to the technical records.	☐
2.	☒	☐	☐	☐	EC-type examination and/or the certification are still valid	☐
3.	☒	☐	☐	☐	The approvals for operating procedures employed are still valid.	☐
4.	☒	☐	☐	☐	The approvals for joining personnel are still valid.	☐
5.	☒	☐	☐	☐	The approvals for NDT personnel are still valid.	☐
6.	☒	☐	☐	☐	The qualifications for other personnel are still valid.	☐
7.	☒	☐	☐	☐	There have been no changes in the application and the use of production methods and equipment.	☐
8.	☒	☐	☐	☐	Appropriate methods to ensure the traceability of materials are applied.	☐
9.	☒	☐	☐	☐	Initial inspections are performed according to Directive 1999/36 EC	☐
10.	☒	☐	☐	☐	Marking / labeling is performed according to Directive 1999/36/EC.	☐
11.	☒	☐	☐	☐	The operating manual is issued and given with the pressure equipment.	☐

E = satisfied; TE = partly satisfied (see attached sheet); NE = not satisfied (see attached sheet); NZ = not applicable

2. Checks:

☒	Checks on the pressure equipment were performed during the unexpected visit.
☒	The test reports have been handed out to the manufacturer.
☒	The manufacturer was obliged to communicate the production program planned so that the check during the unexpected visits can be performed.

TÜV Industrie Service GmbH · TÜV SÜD Group
Notified Body 0036 according to PED
Location: Istanbul, on 23.05.2011

Attachment: ☐ Appendix
Distributor: ☒ Manufacturer
☐ PED-QS-Certification body
☐ Document

For the test laboratory:

Local certifier:

Özlük, Hakim

Surname Name, organization unit

Surname Name, organization unit



Türkiye

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-14-11-5010281905-001-14-B-01236
Certificate No.:

Name und Anschrift

Name and postal address of manufacturer:

UMB MÜHENDİSLİK PROJE MAKİNA İNŞ.
ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN.
İÇ VE DIŞ TİC. LTD. ŞTİ.
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.:

Test report No.:

P-IS-TGK-IST-14-11-5010281905-001-14-B-01236

Geltungsbereich:

Scope of examination:

70 Lt Steam Generator with 3,2 Bar PS and 5 Bar PT
Drawing No: Buhar Jenaratörü 1 Rev. 1
Approved by TÜV SÜD Designer at date 21.11.2014

Fertigungsstätte:

Manufacturing plant

İvogsan 1472. Sok. No:72 OSTİM
ANKARA/ TURKEY

Istanbul, 21.11.2014
(Ort, Datum)



TÜV SÜD Industrie Service GmbH
TÜV SÜD Gruppe
TÜV CERT-Zertifizierungsstelle
für Druckgeräte

(Hakim ÖZLÜK)
Benannte Stelle, Kennnummer 0036



Industrie Service

TÜV Süd TGK

Büyükdere Cad. Şarlı İş Merkezi, No:103/A, Kat:5 , TR-34394 Mecidiyeköy- İstanbul

Prüfbericht – Nr.: P- IS-TGK-IST-14-11-5010281905-001-14-B-01236

Technical File examination according to directive 97/23/EC

Auftraggeber: TÜV SÜD
Commissioned by: Büyükdere Cad. Şarlı İş Merkezi No:103/AKat:5
TR-34394 Mecidiyeköy- İstanbul
Hersteller: UMB MÜHENDİSLİK PROJE MAKİNA İNŞ.
Manufacturer: ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN.
İÇ VE DIŞ TİC. LTD. ŞTİ.
İvogsan 1472. Sok. No:72 OSTİM
ANKARA/TURKEY

Prüfobjekt: STEAM GENERATOR
Test Item:

Prüfgrundlage: EN13445-3/ 97/23 EC
Basis of Examination:

Zeichnungs-Nr.: Buhar Jenaratörü 1 Rev.1
Drawing No:

Auftrag Nr.: 14-B-01236
Commission No:

Auslegungsdaten:
Design Data:

max. zul. druck (PS) max.allowable pressure	bar	3,2
max. zul. Temp (TS) max.allowable temperature	C	20/141
Inhalt capacity	liter	70
Heizfläche heating surface	m2	N/A
zul. Dampferzeugung adm.steam quantity	kg/h	N/A
Prüfdruck (PT) test pressure	bar	5

Konformitäts- Modul B
bewertungsverfahren Fluidgruppe 2

Conformity assesment procedure

Anlagen Steam Generator

annex technical file,

TÜV Süd Teknik Güvenlik ve Kalite Denetim Sanayi ve Ticaret Ltd.Şti.

TÜV SÜD Group

Telefon : (0212) 347 98 10 / pbx Telefax : (0212) 347 98 11

e-mail : info@tuv-tgk.com

Ticaret Sicili: 232461 / 180027



Industrie Service

TÜV Súd TGK

Büyükdere Cad.Şarlı İş Merkezi, No:103/A, Kat:5 , TR-34394 Mecidiyeköy– İstanbul

Dear Sirs,

According to your order, dated 31.10.2014, we have evaluated the document (type evaluation) in Module B of the pressure equipment directive 97/23/EC (PED). Result of our evaluation was:

- ... No special objections were found.
- ... Please observe our additional notes and our remarks in the drawing.
- ... A re-evaluation is not required.
- ... The particular material appraisal was based on the applied technical specification EN.
- ... Deviations, additions to or exclusions from the test specification: none
- ... Non-standart test methods or procedures utilised: none
- ... Utilised measurements, examinations and derived results: none

Additional notes:

- ... Design is based on EN 13445-3. All documentation and testing during final assesment should be inspected.
- ... Manufacturing records, test reports of first manufactured vessel should be included in technical file.
- ... Calculations of vessel should be included in technical file.
- ... Bolt and nut material should be according to EN 13445.
- ... No external loads are considered on calculations.
- ... No nozzle loads are considered on calculations.
- ... Those documents and information should be inspected in technical file:
 - Vessel handling-transportation-erection methode.
 - Erection site conditions (ambient temperature, wind, earthquake)
 - Lifting procedure
 - Safety valve set point-capacity and location.

TÜV Súd Teknik Güvenlik ve Kalite Denetim Sanayi ve Ticaret Ltd.Şti.

TÜV SÜD Group

Telefon : (0212) 347 98 10 / pbx Telefax : (0212) 347 98 11

e-mail : info@tuv-tgk.com

Ticaret Sicili: 232461 / 180027



Industrie Service

TÜV Súd TGK

Büyükdere Cad.Şarlı İş Merkezi, No:103/A, Kat:5 , TR-34394 Mecidiyeköy- İstanbul

... Those documentation should be inspected in vessel manufacturing file during final assesment:

- Welder certificates
- Welding procedure specifications
- Material certificates
- NDT personnel qualification,
- Material tracebility records,
- Dimension control records with tolerances

... If plates are flame-cut, grinding-machining should be applied

... If hydrostatic test is applied by pnomatic, a safety procedure should be applied

We keep one set of technical file for our documentation.

The invoice in connection with this evaluation will be send seperately.

The results of evaluation are valid only for the documents referred to hereunder. Reproduction of this report except a reproduction in full requires our written approval.

With best regards

Tüv Súd Industrie Service

Hakim ÖZLÜK

Mutlu DEMİR



Benannte Stelle, Kennnummer 0036

Istanbul, 21.11.2014

Enclosure:

1 set of **Steam Generator UMB MÜHENDİSLİK PROJE MAKİNA İNŞ. ÇEVRE VE TIBBİ CİHAZLAR İMALAT SAN. İÇ VE DIŞ TİC. LTD. ŞTİ.**

technical file.

TÜV Súd Teknik Güvenlik ve Kalite Denetim Sanayi ve Ticaret Ltd.Şti.

TÜV SÜD Group

Telefon : (0212) 347 98 10 / pbx Telefax : (0212) 347 98 11

e-mail : info@tuv-tgk.com

Ticaret Sicili: 232461 / 180027