COPIA CORESPUNDE ORIGINALULUI

RIMSA

DICHIARAZIONE CE DI CONFORMITA' DEL COSTRUTTORE

La società: **RIMSA P. LONGONI S.r.l.**
Via Monterosa, 18/20/22 - 20831 SEREGNO (MB) - ITALIA

dichiara sotto la propria responsabilità che i Dispositivi Medici prodotti nell'anno 2020:

Modello: **PENTALED 30N**

Versioni	mod. Pentaled 30N SO (dispositivo a soffitto)
	mod. Pentaled 30N PI (dispositivo a piantana)
	mod. Pentaled 30N PA (dispositivo a parete)
	mod. Pentaled 30N +30N (dispositivo a soffitto doppio)

costruiti da RIMSA P.LONGONI S.r.l., sono conformi:

- *all'Allegato VII della Direttiva 93/42/CEE del 14/05/1993, applicata in Italia dal Decreto Legislativo N.46 del 24 Febbraio 1997 e successive varianti (inclusa la Direttiva 2007/47/CE del 05/09/2007, applicata in Italia dal Decreto Legislativo N.37 del 25 Gennaio 2010) e alle seguenti norme:*

  - IEC 60601-1 (Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali)
  - IEC 60601-2-41 (Parte 1: Norme particolari relative alla sicurezza fondamentale e alle prestazioni essenziali delle lampade scialitiche per uso chirurgico e per la diagnosi)
  - IEC 60601-1-2 (Parte 2: Prescrizioni generali per la sicurezza fondamentale e prestazioni essenziali- Norma collaterale: Compatibilità elettromagnetica – Prescrizioni e prove)

  - Classificazione in riferimento all'articolo 9 e allegato IX della Direttiva 93/42/CEE e 2007/47/CE
    Durata: Breve termine (Allegato IX,Par.1 "Definizioni", art.1, comma 1.1)
    Descrizione: Disp. Medico non invasivo (Allegato IX, Par.1 "Definizioni", art.1, comma 1.2)
    Disp. Medico attivo (Allegato IX, Par.1 "Definizioni", art.1, comma 1.4)
    CLASSE: Classe I (Allegato IX, par.3 "Classificazione", art.3, comma 3.3, Regola 12) e
    (Allegato IX Par.3 "Classificazione", art.1, comma 1.1 Regola 1)
  - Riferimento fascicolo tecnico Cod. RIM-FT008.
  - La valutazione di conformità è sviluppata in riferimento all'articolo 11 della Direttiva 93/42/CEE e 2007/47/CE.

Il Sistema Qualità di RIMSA è conforme alle norme UNI EN ISO 9001 e UNI CEI EN ISO 13485 ed è certificato da CSQ (certificato CSQ n.9120.RMS1 e 9124.RMS2).

Seregno, 07/01/2020
Luogo e data

RIMSA - P. LONGONI S.r.l.
Timbro e firma del Consigliere Delegato
(Paolo Longoni)

"ROMEDCOM"

RIMSA

COPIA CORESPUNDE ORIGINALULUI

MANUFACTURER'S DECLARATION OF CONFORMITY CE

The company **RIMSA P. LONGONI S.r.l.**
Via Monterosa, 18/20/22 - 20831 SEREGNO (MB) - ITALY

declares on its own responsibility that the Medical Devices made in the year 2020:

Model: **PENTALED 30N**

Versions	mod. Pentaled 30N SO (ceiling device)
	mod. Pentaled 30N PI (mobile device)
	mod. Pentaled 30N PA (wall device)
	mod. Pentaled 30N+30N (double-ceiling device)

constructed by RIMSA P.LONGONI S.r.l., conforms:

- *to the Attachment VII of the 93/42/EEC Directive of May 14th 1993, and subsequent variations (including the 2007/47/EC Directive of September 5th 2007); moreover, it is in conformity with the following safety regulation:*

  - IEC 60601-1 (Part 1: General requirements for basic safety and essential performance)
  - IEC 60601-2-41 (Part 2: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis)
  - IEC 60601-1-2 (Part 1: General requirements for basic safety and essential performance – collateral standard: Electromagnetic compatibility - Requirements and tests)

  - Classification with reference to article 9 and Attachment IX of 93/42/EEC Directive and 2007/47/EC
    Duration : Short term (Annex IX, Par.1 "Definitions", art.1, sub-section 1.1)
    Description: Non invasive Medical Device (Annex IX, Par.1 "Definitions", art.1, sub-section 1.2)
    Active Medical Device (Annex IX, Par.1 "Definitions", art.1, sub-section 1.4)
    Class: Class I (Annex IX, Par.3 "Classification", art.3, sub-section 3.3, Rule 12)
    (Annex IX, Par.3 "Classification", art.1, sub-section 1.1, Rule 1)
  - Reference to technical file Code RIM-FT018.
  - The conformity assessment is developed in reference to article 11 of the 93/42/EEC Directive and 2007/47/EC.

RIMSA Quality System conforms to the UNI EN ISO 9001 and UNI EN ISO 13485 regulations and is certified by the CSQ (certified CSQ n.9120.RMS1 and 9124.RMS2).

Seregno, 07/01/2020

Place and date

RIMSA - P. LONGONI S.r.l.

Mark and sign of Managing Director
(Paolo Longoni)

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ROMEDCOM" S.R.L. REPUBLICA MOLDOVA IDNO: 1004600066875

COPIA CORESPUNDE ORIGINALULUI

CISQ

www.imq.it

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. / *CERTIFICATE N.* 9124.RMS2

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

RIMSA P. LONGONI SRL

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e fabbricazione di dispositivi medici elettromedicali di illuminazione per sala operatoria e per osservazione
Design and manufacture of medical electrical equipments, surgical luminaires and luminaires for diagnosis

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2001-11-15	2019-09-12	2022-11-14

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

S.R.L. "ROMEDCOM" IDNO: 1004600066975 SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA

IMQ

FEDERAZIONE CISQ
www.cisq.com

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

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www.imq.it

CERTIFICATO N. / *CERTIFICATE N.* 9120.RMS1

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

RIMSA P. LONGONI SRL

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e fabbricazione di dispositivi medici elettromedicali di illuminazione per sala operatoria e per osservazione e apparecchi tecnici di illuminazione
Design and maufacture of medical electrical equipments, surgical luminaires and luminaires for diagnosis and technical lighting devices

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2001-11-15	2019-09-12	2022-11-14

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

S.R.L. "ROMEDCOM" IDNO 1004600066975

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FEDERAZIONE CISQ
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CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

IAF: 19

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

Organismo di Certificazione Federato CISQ
www.imq.it

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

***CISQ/IMQ** has issued an IQNet recognized certificate that the organization:*

RIMSA P. LONGONI SRL

VIA MONTEROSA 18/20/22 - 20831 SEREGNO (MB)

has implemented and maintains a

Quality Management System

for the following scope:

Design and maufacture of medical electrical equipments, surgical luminaires and luminaires for diagnosis and technical lighting devices

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: ***2019 - 09 - 12***

Expires on: ***2022 - 11 - 14***

This attestation is direcly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 20641

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
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IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

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CERTIFICATE

Quality Management System as per TS EN ISO 9001:2015

In accordance with BBS Belgelendirme Eğitim ve Gözetim Hizmetleri A.Ş. procedures, it is hereby certified that

eryiğit

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

İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453. Sk. No: 3 Ostim – Yenimahalle / ANKARA

Applies a management system in line with the above standard for the following scope

Design, Manufacture, Sales And Servicing Of Central Sterilization Units, Steam Sterilizers, Combined Formaldehyde Sterilizators With Steam, Gas Sterilizators With Ethylene Oxide, Hydrogen Peroxide Gas Plasma Sterilizers, Laboratory Type Perpendicular Autoclave, Surgical Washing And Disinfection Devices, Surgery Tables And Traction Kits, Surgery Ceiling Lamps, Gynecologic, Urologic, Delivery And Examination Tables, Hospital Sterilization Stainless Equipments, Ent Chair, Oxygen Production And Storage Systems, Water Treatment Systems And Diesel Engines–NO_x Reduction Agent AUS 32.

Certificate No: 007-01

Initial Certification 06.09.2018
Valid until 05.09.2021

Certification Body
at BBS A.Ş.

Ankara, 06.09.2018

This certification was conducted in accordance with BBS A.Ş. auditing and certification procedures and is subject to regular surveillance audits.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

TÜRKAK
Kalite Yonetim Sistemi
TS EN ISO/IEC 17021
AB-0021-YS

TÜRKAK BDS NO
YS-D295-52EC

The authenticity of this certificate may be verified at www.bbsas.com.tr and tbds.turkak.org.tr.
The authenticity may also be checked with the QR Code above.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Kabil Caddesi 1328 Sokak No:8/9 TR-06460 ÇANKAYA / ANKARA
www.bbsas.com.tr

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kiwa

CERTIFICATE

eryiğit

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

İVEDİK ORGANİZE SANAYİ BÖLGESİ ÖZ ANADOLU SİTESİ 1453. SOK. NO:3 OSTİM YENİMAHALLE – ANKARA – TURKEY

with a scope of

DESIGN, MANUFACTURE AND SERVICING OF CENTRAL STERILIZATION UNITS, STEAM STERILIZERS, HYDROGEN PEROXIDE GAS PLASMA STERILIZERS, LABORATORY TYPE PERPENDICULAR AUTOCLAVE, SURGICAL WASHING AND DISINFECTION DEVICES, SURGERY TABLES AND TRACTION KITS, SURGERY CEILING LAMPS, GYNECOLOGIC, UROLOGIC, DELIVERY AND EXAMINATION TABLES, HOSPITAL STERILIZATION STAINLESS STEEL EQUIPMENTS ENT CHAIR, OXYGEN PRODUCTION AND STORAGE SYSTEMS

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"6.4.2" "7.5.2" "7.5.5" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 7762
Initial Certification Date	: 28 January 2010
Certification Date	: 08 January 2019
Expiration Date	: 07 January 2022

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-E8A8-8605

S.R.L. "ROMEDCOM" RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, SOCIETATEA CU IDNO 1004600066975

General Manager

Kiwa Certification Services Inc.
İTOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-013

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

ERYİĞİT ENDÜSTRİYEL MAKİNE VE TIBBİ CİHAZLAR İMALAT İTHALAT İHRACAT İNŞAAT TİCARET ANONİM ŞİRKETİ

İvedik Organize Sanayi Bölgesi Öz Anadolu Sitesi 1453. Sok. No:3 06370 Ostim, Ankara, Turkey

Products: Steam sterilizers, Hydrogen peroxide plasma sterilizers, Washer disinfectors, Oxygen production and storage systems

The products defined at the enclosure which is the part of this certificate and contains two pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.2927.09
Date of first issue:	25 February 2010
Date of last issue:	16 April 2018
Revision Number:	07
Expiry Date:	07 February 2021

16 April 2018, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-10-013, Revision Number: 07
Concerned medical devices;

Product: Steam sterilizers

Types	Models
ERS, STR	75, 75V, 4407S, 4407V, 4410V, 4410S, 5510S, 5510V, 5510D, 5512S, 5512V, 5512D, 6610S, 6610V, 6610D, 6613S, 6613V, 6613D, 7712S, 7712V, 7712D, 7715S, 7715V, 7715D, 7717S, 7717V, 7717D, 2000S, 2000V, 2000D
GOLDBERG	75, 75V, 120S, 120V, 160S, 160V, 250S, 250V, 250D, 300S, 300V, 300D, 422S, 422V, 422D, 550S, 550V, 550D, 675S, 675V, 675D, 840S, 840V, 840D, 1000S, 1000V, 1000D, 2000S, 2000V, 2000D

Product: Hydrogen peroxide plasma sterilizers

Types	Models
TEKSTERİL	TSP 80, TSP 120, TSP 135, TSP 160, TSP 200
GOLDBERG	GP 80, GP 120, GP 135, GP 160, GP 200

Product: Washer disinfectors

Types	Models
TEKSTERİL	TSY 150, TSY 225, TSY 290M, TSY 290O, TSY 360, TSY 3000
GOLDBERG	GY 150, GY 225, GY 290M, GY 290O, GY 360, GY 3000

16 April 2018, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

COPIA CORESPUNDE ORIGINALULUI

DECLARATION OF CONFORMITY ACCORDING TO MDD 93 / 42 / EEC – 2007 / 47 / EC

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

Address : Özanadolu Sanayi Sitesi 1453. Sok. No: 3 06370 Ostim, Yenimahalle, ANKARA TURKEY

Tel / Fax : +90 312 395 57 95 / +90 395 57 96

Web / Eposta : www.eryigit.com.tr / info@eryigit.com.tr

Product : Operating Table for General Surgery, Gynecological & Urological Examination Table, Gynecological Obstetric Table

Classification: Class I according to Medical Devices Directive, Appendix VII, Rule I

We hereby declare that the products, as specified below in the attached list; Operating Tables for General Surgery, Gynecological & Urological Examination Table, Gynecological Obstetric Table products with all accessories carry CE Mark according to EU MDD 93/42/EEC, and 2007 / 47 / EC Appendix 2.3, as being valid from the date of March 3rd, 2018.

Attached List

<table>
<tr><th colspan="8">DIRECTIVES and CE CLASSIFICATION of STERILIZER</th></tr>
<tr><td colspan="2">EC Directive</td><td colspan="6">MDD 93/42/EEC – 2007/47/EC – Appendix II – Article VII and Rule 1</td></tr>
<tr><td rowspan="2">Medical Device and/or Accessories Name or Description</td><td rowspan="2">Brand</td><td rowspan="2">Model No</td><td rowspan="2">GMDN Product Code</td><td rowspan="2">UNSPC Product Code</td><td rowspan="2">Classification</td><td colspan="2">Is the Medical Device Sterile?</td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td rowspan="2">Operating Table for General Surgery, Gynecological & Urological Examination Table, Gynecological Obstetric Table</td><td>ERM STR</td><td>200 D, 203 T, 201, 202, 203, 203 T, 204,200 D, 2000, 2000F</td><td rowspan="2">36867</td><td rowspan="2">42295112</td><td rowspan="2">I</td><td></td><td rowspan="2">X</td></tr>
<tr><td>GOLDBERG</td><td>5S, 6S</td></tr>
<tr><td>List of Applied Standards:</td><td colspan="7">EN60601-1, EN60601-1-2, EN62304, TS EN 60601-2-46, EN 15223-1, TS EN 60601-2-38, ISO 9001, ISO 13485</td></tr>
</table>

S.R.L. "ROMEDCOM" IDNO 1004600068975 SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA

eryiğit
TIBBİ CİH.İML.İTH.HR.İNŞ.TİC.A.Ş.
Özanadolu Sanayi Sit. 1453. Sok. No:3
İvedik OSB Yenimahalle ANKARA
(312) 395 57 95 (pbx) Faks (0312) 395 57 96
Ulus Vergi Dairesi 377 041 6084