



CERTIFICATE



AT Sertifikası
Tam Kalite Güvence Sistemi
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3

Sertifika Numarası: 1984-MDD-21-738

Aşağıda bahsi geçen kuruluşun tam kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-II (Bölüm 4 muaf tutularak) gereksinimlerine göre yapıldığını beyan ederiz. Tam kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

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, Türkiye

Ürünler: Buhar Sterilizatörü, Yıkama ve dezenfeksiyon cihazı, Oksijen Üretim ve Depolama Sistemi, Hidrojen Peroksit Gaz Plazma Sterilizatörü

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek bir sayfadan oluşmaktadır. Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No: M.2927.12

Son Geçerlilik Tarihi: 27 Mayıs 2024

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

12 Şubat 2021, İstanbul, Türkiye



AT Sertifika Eki:

Sayfa 1/1

Tam Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3

Sertifika No: 1984-MDD-21-738

İlgili tıbbi cihazlar;

Ürün: Buhar Sterilizatörü

Tipleri	Model Adı
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

Ürün: Yıkama ve Dezenfeksiyon Cihazı

Tipleri	Model Adı
TEKSTERİL	TSY 150, TSY 225, TSY 290M, TSY 2900, TSY 360, TSY 3000
GOLDBERG	GY 150, GY 225, GY 290M, GY 2900, GY 360, GY 3000

Ürün: Oksijen Üretim ve Depolama Sistemi

Tipleri	Model Adı
GOLDBERG	Oxy-Gold 2, Oxy-Gold 3, Oxy-Gold 4, Oxy-Gold 5, Oxy-Gold 7, Oxy-Gold 11, Oxy-Gold 15, Oxy-Gold 18, Oxy-Gold 22, Oxy-Gold 30, Oxy-Gold 37, Oxy-Gold 45, Oxy-Gold 55, Oxy-Gold 75, Oxy-Gold 90, Oxy-Gold 110, Oxy-Gold 132, Oxy-Gold 160, Oxy-Gold 200, Oxy-Gold 250, Oxy-Gold Poliklinik10, Oxy-Gold Ambulans10, Oxy-Gold M10, Oxy-Gold M20, Oxy-Gold M30, Oxy-Gold M40, Oxy-Gold K4, Oxy-Gold K5, Oxy-Gold K7, Oxy-Gold K11, Oxy-Gold K15, Oxy-Gold K18, Oxy-Gold K22, Oxy-Gold K30, Oxy-Gold K37

Ürün: Hidrojen Peroksit Gaz Plazma Sterilizatörü

Tipleri	Model Adı
TEKSTERİL	TSP 80, TSP 120, TSP 135, TSP 160, TSP 200
GOLDBERG	GP 80, GP 120, GP 135, GP 160, GP 200

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

12 Şubat 2021, İstanbul, Türkiye



CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-21-738

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, Washer disinfectors, Oxygen Production and Storage Systems, Hydrogen Peroxide Gas Plasma Sterilizer

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

Report Number: M.2927.12
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

12 February 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

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

Certificate Number: 1984-MDD-21-738

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: Washer disinfectors

Types	Models
TEKSTERİL	TSY 150, TSY 225, TSY 290M, TSY 2900, TSY 360, TSY 3000
GOLDBERG	GY 150, GY 225, GY 290M, GY 2900, GY 360, GY 3000

Product: Oxygen production and storage systems

Types	Models
GOLDBERG	Oxy-Gold 2, Oxy-Gold 3, Oxy-Gold 4, Oxy-Gold 5, Oxy-Gold 7, Oxy-Gold 11, Oxy-Gold 15, Oxy-Gold 18, Oxy-Gold 22, Oxy-Gold 30, Oxy-Gold 37, Oxy-Gold 45, Oxy-Gold 55, Oxy-Gold 75, Oxy-Gold 90, Oxy-Gold 110, Oxy-Gold 132, Oxy-Gold 160, Oxy-Gold 200, Oxy-Gold 250, Oxy-Gold Poliklinik10, Oxy-Gold Ambulans10, Oxy-Gold M10, Oxy-Gold M20, Oxy-Gold M30, Oxy-Gold M40, Oxy-Gold K4, Oxy-Gold K5, Oxy-Gold K7, Oxy-Gold K11, Oxy-Gold K15, Oxy-Gold K18, Oxy-Gold K22, Oxy-Gold K30, Oxy-Gold K37

Product: Hydrogen Peroxide Gas Plasma Sterilizer

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

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

12 February 2021, Istanbul, Turkey