CERTIFICATE

# EC Certificate

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

**Certificate Number: 1984-MDD-11-102**

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:**

**AYGÜN CERRAHİ ALETLER SANAYİ VE TİCARET ANONİM ŞİRKETİ**

Kerimbey OSB Mahallesi Yaşardoğu Cad. No:76/1 Tekkeköy, Samsun, Turkey

**Products:** Electrical and battery operated surgical motor system, High speed surgical motor system, Electrical and pneumatical surgical motor systems, Surgical power system

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.3608.10 |
| **Date of first issue:** | 05 July 2011 |
| **Date of last issue:** | 17 May 2021 |
| **Revision Number:** | 09 |
| **Expiry Date:** | 27 May 2024 |

Muhteşemm Gökhan Yücel
Head of Notified Body

17 May 2021, Istanbul, Turkey

**Kiwa Belgelendirme Hizmetleri A.Ş.**
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-11-102, Revision Number: 09**

Concerned medical devices;

**Product:** Electrical and battery operated surgical motor system
**Model Name:** Praxis 3, BES Dermatome, Dermatome ST-5, Karınca 206, Karınca 208, Praxis 3B, Raptor SPS 4

**Product:** High speed surgical motor system
**Model Name:** HSM-2, HSM-2 Mini Bone

**Product:** Electrical and pneumatical surgical motor systems
**Model Name:** Electrical Control Unit (M6-034), Pneumatic Surgical Motor

**Product:** Surgical power system
**Model Name:** Scoren

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

Muhteşemm Gökhan Yücel
Head of Notified Body

17 May 2021, Istanbul, Turkey

**Kiwa Belgelendirme Hizmetleri A.Ş.**
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# MDCG 2020-3 Change Verification Form

| | |
|---|---|
| **Date:** | 30.11.2021 |
| **Reference No:** | MY-21-002021 |

Dear Sir/Madam,

Your following proposed change is reviewed according to the MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

| **Information on EC Certificate** | |
|---|---|
| EC Certificate No: | 1984-MDD-11-102 |
| Revision: | 1984-MDD-11-102 Rev. 09 (17 Mayıs 2021) |
| Manufacturer: | AYGÜN CERRAHİ ALETLER SANAYİ VE TİCARET ANONİM ŞİRKETİ |
| Expiry Date: | 27.05.2024 |
| **Information on Proposed Change** | |
| Subject of Change: | Electrical and pneumatic surgical motor systems products are removed the from certificate. |

The implementation of the above change proposed by AYGÜN CERRAHİ ALETLER SANAYİ VE TİCARET ANONİM ŞİRKETİ does not represent a significant change in the design and usage purpose within the scope of MDR Article 120(3).

The above-mentioned EC certificate is valid until its expiration date and is subject to the successful completion of periodic surveillance audits.

This letter is valid when presented together with the EC Certificate mentioned above.

Sincerely,

Orhan Karakuş
Quality Manager



Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No:15 Tepeören Tuzla - İstanbul / Türkiye
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# MDCG 2020-3 DEĞİŞİKLİK DOĞRULAMA FORMU
## *MDCG 2020-3 Change Verification Form*

| | |
|---|---|
| **Tarih:** ***Date:*** | 28.03.2023 |
| **Referans No:** ***Reference No:*** | MY-23-002432 |

Sayın Yetkili,

Tıbbi Cihaz Yönetmeliği ((AB) 2017/745) Madde 120 ve MDCG 2020-3 MDD veya AIMDD uyarınca düzenlenen sertifikaların kapsadığı cihazlarla ilgili olarak MDR Madde 120'de tanımlanan geçiş hükmünde belirtilen önemli değişikliklere ilişkin rehber dokümanına göre tarafımıza bildirilen aşağıdaki değişiklik önerisi incelenmiştir.

*Dear Sir/Madam,*

*Your following proposed change is reviewed according to the MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.*

| **EC Sertifika Bilgileri** ***Information on EC Certificate*** | |
|---|---|
| EC Sertifika No: *EC Certificate No:* | 1984-MDD-11-102 |
| Revizyon bilgileri: *Revision:* | 1984-MDD-11-102 Rev.09 (17.05.2021) |
| İmalatçı : *Manufacturer:* | AYGÜN CERRAHİ ALETLER SANAYİ VE TİCARET ANONİM ŞİRKETİ |
| Son Geçerlilik Tarihi: *Expiry Date:* | 27.05.2024 |
| **Değişiklik Önerisine İlişkin Bilgiler** ***Information on Proposed Change*** | |
| Değişiklik konusu: *Subject of Change:* | **Adres Yazım Değişikliği**<br>Eski Adres: Kerimbey OSB Mahallesi Yaşardoğu Cad. No:76/1 Tekkeköy, Samsun,Türkiye<br>Yeni Adres: Kerimbey Organize Sanayi Mh. Yaşar Doğu Cd. No: 76/1 Tekkeköy, Samsun, Türkiye<br><br>***Address Spelling Change***<br>*Old Address: Kerimbey OSB Mahallesi Yaşardoğu Cad. No:76/1 Tekkeköy, Samsun,Türkiye*<br>*New Address: Kerimbey Organize Sanayi Mh. Yaşar Doğu Cd. No: 76/1 Tekkeköy, Samsun, Türkiye* |

AYGÜN CERRAHİ ALETLER SANAYİ VE TİCARET ANONİM ŞİRKETİ tarafından önerilmiş olan yukarıdaki değişikliğin uygulanması MDR Madde 120(3) kapsamında tasarım ve kullanım amacında önemli değişiklik oluşturmamaktadır.
*The implementation of the above change proposed by* AYGÜN CERRAHİ ALETLER SANAYİ VE TİCARET ANONİM ŞİRKETİ *does not represent a significant change in the design and usage purpose within the scope of MDR Article 120(3).*

Yukarıda belirtilen EC sertifikası son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir.
*The above-mentioned EC certificate is valid until its expiration date and is subject to the successful completion of periodic surveillance audits.*

Bu yazı yukarıda belirtilen EC Sertifikası ile beraber sunulduğunda geçerlidir.
*This letter is valid when presented together with the EC Certificate mentioned above.*

Saygılarımızla / *Sincerely,*

Kiwa İSTANBUL TÜRKİYE

Orhan Karakuş
Kalite Müdürü / *Quality Manager*



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