



T.C.
SAMSUN İLİ
HUKUK İŞLERİ ŞUBE MÜDÜRLÜĞÜ

Resmi Mühürün SAMSUN TİCARET VE SANAYİ ODASI'ne
 İmzanın da VAHİDE DAMLA ÖZDEN'a
 Ait Olduğu Tasdik Olunur.
 İşbu Tasdik Metne Şamil Değildir.

Tasdik No : 147
 28.01.2021
 Zerrin ÖĞÜT
 ŞUBE MD.

REPUBLIC OF TURKEY
 MINISTRY OF FOREIGN AFFAIRS
 Directorate General for Consular Affairs

SAMSUN VALİLİĞİ

THIS CERTIFICATION DOES NOT COVER THE CONTENT
 AND THE AUTHENTICITY OF THIS DOCUMENT.

Number: - 02120
 Ankara, 03 Subat 2021

Sema COŞAROĞLU
 İkinci Kaptan

CER

Medical devices - Quality management systems
 regulatory purposes

"Following elements of the standard are excluded"
 "7.5.5" "7.5.7" "7.5.9.2"

EN ISO 13485:2016



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



TÜRKAK BDS NO
 YS-C267-70CD

ĐẠI SỨ QUÁN NƯỚC CHHON VIET NAM TẠI THỎ NHÍ KỲ
 EMBASSY OF THE S.R OF VIETNAM IN TURKEY

CHỨNG NHẬN / HỢP PHÁP HOÁ LÃNH SỰ
 CONSULAR AUTHENTICATION

1. Quốc gia / Country: Viet Nam

2. do Ông (Bà): Sema COŞAROĞLU
 has been signed by Viên chức Lãnh sự KỲ

3. với chữ danh: Viên chức Lãnh sự KỲ

4. và con dấu của: Vu Lãnh sự Bộ Ngoại giao
 bears the seal/stamp of CH THỎ NHÍ KỲ

được chứng nhận / hợp pháp hoá lãnh sự
 Certified the

5. tại / at: Ankara 6. ngày / day: 04.02.2021

7. Cơ quan cấp: ĐÀI SỨ QUÁN NƯỚC CHHON VIET NAM TẠI THỎ NHÍ KỲ
 Embassy of the S.R of Vietnam in Turkey

8. Số / No: 208/LS-ĐSA

Ký tên và đóng dấu
 signature and seal/stamp

BI THỦ THỦ NHẬT
 Thủ trưởng
 Nguyễn Phú Loan Hoàng

CNJSO



CERTIFICATE

AYGÜN[®]
SURGICAL INSTRUMENTS CO., INC.
AYGÜN CERRAHİ ALETLER
SANAYİ VE TİCARET A.Ş.

KERİMBEY OSB MAH. YAŞAR DOĞU CAD. NO: 76/1 55330
TEKKEKÖY – SAMSUN – TURKEY

with a scope of

**DESIGN, DEVELOPMENT, MANUFACTURING AND DISTRIBUTION
OF ELECTRICAL, PNEUMATIC AND BATTERY OPERATED
SURGICAL MOTOR SYSTEMS, SURGICAL ILLUMINATION
SYSTEMS AND STERILISATION CONTAINERS**

Medical devices - Quality management systems - Requirements for
regulatory purposes

"Following elements of the standard are excluded"
"7.5.5" "7.5.7" "7.5.9.2"

EN ISO 13485:2016

Certificate No : M 8693
Initial Certification Date : 05 July 2011
Certification Date : 01 June 2020
Expiration Date : 31 May 2023



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



TÜRKAK BDS NO
YS-C267-70CD

General Manager

Kiwa Certification Services Inc.

ITOSB 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.

Last Modified: 01 June 2020 - R 05

KIWS



AYGUN
 MEDICAL INSTRUMENTS CO. LTD.
 AYGUN CERRAHI ALTER
 SAHAYI VE TICARET A.S.

KENTREY OSB MIAK YAZAR DOGU CAD NO: 17A
 TICARET - SAMSUN - TURKEY

DESIGN, DEVELOPMENT, MANUFACTURING AND DISTRIBUTION
 OF ELECTRICAL, PNEUMATIC AND BATTERY OPERATED
 SURGICAL MOTOR SYSTEMS, SURGICAL ILLUMINATION
 SYSTEMS AND STERILIZATION CONTAINERS

Medical device - Quality management systems - Regulatory affairs



THE COMPANY IS A MEMBER OF SAMSUN CCI
 PRESENT APPROVAL DOES NOT COVER THE
 CONTENT OF THE DOCUMENT FOR SAMSUN
 CHAMBER OF COMMERCE AND INDUSTRY

V. Damla GYDEN
 Foreign Affairs Expert
 Samsun CCI

20 JAN 2021

