



Certificate

EC DECLARATION OF CONFORMITY

This Is To Certify That The Following Products Of :

RENASAN MÜREKKEPLİ ŞERİTLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

ERGAZİ MAHALLESİ 1819. CADDE NO:3/D YENİMAHALLE / ANKARA

This is to certify that the product

Your suitability has been evaluated by IQM Certification and has submitted Declaration of Conformity (Dated: 06/06/2020) according to Class 1 -Medical Devices Directive 93/42/EEC- 2007/47/EC- Annex IX It Iso 13485 : 2016 Medical Devices Quality Management System has been determined that the system and security requirements have been met.

Verified technical construction file, test reports and declaration of conformity signed by the manufacturer and found to be complied with above directives and standards.

For the Products of

%70 isopropanol wipes for use in pre injection disinfection and skin and hand cleaning %70 ethanol wipes for use in pre injection disinfection and skin and hand cleaning (NON STERILE- STERİL OLMAYAN) Product Commercial Brand / Marka: RENASAN Alkollü Swap Mendil

Above statement loses its validity if the equipment undergoes any changes not authorized in writing by the manufacturer.

Certificate Number: IQM-CE-0829

This certificate of compliance is valid from 16.05.2023 to 24.06.2024



GENERAL MANAGER

AT UYUM BEYANI
(DECLARATION of CONFORMITY)



Aşağıda listelenen ürünlerimizin "Avrupa uyumluluk Komisyonu" nun (MDD 93/42/EEC)-(2007/47/EC-EK IX) nolu direktifini karşıladığını BEYAN EDERİZ.

We hereby declare that the following mentioned products meet the provision of the EC Council Directive (MDD 93/42/EEC)-(2004/47/EC-Annex IX)



size özel, tek kullanımlık ürünler sunar.

www.renasan.com.tr - info@renasan.com.tr

Ürün Listesi - List of Products

Antibakteriyel Mendiller – Antibacterial Wipes

Islak Mendiller – Wet Wipes

Tıbbi Swab Mendiller – Alcohol Swabs

Antibakteriyel Jeller – Antibacterial Gel

Muayene Masa Örtüleri – Examination Table Clothes

Ünit Tabla Örtüleri – Unit Table Clothes

Dişçi Hasta Önlükleri – Aprons Dentist Patients

Önlükler – Gowns

Cerrahi Setler – Surgical Set

Hasta Önlükleri – Medical Gowns

Cerrahi Örtüler – Medical Drapes

Üretici (Producer): RENASAN MÜREKKEPLİ ŞERİTLER SANAYİ VE TİCARET A.Ş

Adres (Address): Ergazi Mah. 1819 Cadde No:3-D YENİMAHALLE / ANKARA

Tel : +90 312 255 60 03 (pbx) Fax: +90 312 255 60 23 e-mail: info@renasan.com.tr

Yetkili Kişi (Executive): **REFİK NACİ GİZER** – Yönetim Kurulu Başkanı –CEO

BELGE GEÇERLİLİK BAŞLANGIÇ Tarihi: 01.07.2022

BELGE GEÇERLİLİK SÜRESİ: 01.07.2024



Certificate

RENASAN MÜREKKEPLİ ŞERİTLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

ERGAZİ MAHALLESİ 1819. CADDE NO:3/D
YENİMAHALLE / ANKARA

The IQM Certification approves that the above mentioned organization evaluates the Quality Management System and complies with the requirements of the relevant standard

ISO 9001:2015

Scope,

MANUFACTURING OF ANTIBACTERIAL, DISINFECTANT AND COSMETIC WIPES AND DISPOSABLE MEDICAL PRODUCTS, RESTAURANT CONSUMABLES AND HYGIENIC PRODUCTS

Certificate No.	: IQM-Q-0829
Certificate Initial Issue Date	: 23.05.2022
Certificate Issue Date	: 16.05.2023
Certificate Expire Date	: 22.05.2024

This certificate is valid for a period of three years from the date of initial publication if the IQM documentation rules are followed and the annual surveillance audits are completed successfully. The validity of the certificate will be made every year depends on surveillance control. The validity of the Certificate can be reviewed via www.iqm.com.tr



GENERAL MANAGER



Client Name and address

Müşteri ismi ve adresi

RENASAN MÜREKKEPLİ ŞERİTLER SANAYİ VE TİCARET A.Ş.

ERGAZİ MAH. 1819 CADDE TEKNOSİTE NO:3D BATIKENT – YENİMAHALLE / ANKARA /TÜRKİYE

Standard

Standard

ISO 13485:2016 Quality Management Systems-Medical Devices

INSPECT assessed and approved that related firm meets the requirements of the designated standard at related scope
INSPECT ilgili kuruluşun yukarıda belirtilen standardın gereklerine uygunluğunu ilgili kapsamda tetkik etmiş olup onaylamaktadır.

Scope

Kapsam

DENTAL HASTA ÖNLÜĞÜ – TABLA ÖRTÜSÜ – ALKOLLÜ SWAP MENDİL – MUAYENE MASA ÖRTÜSÜ ÜRETİMİ VE SATIŞI

MANUFACTURING AND SALES OF DENTAL BIBS , DENTAL TABLE CLOTHES , ALCOHOL SWAP WIPES - COUCH ROLLS

IAF / Category Code: A

Initial issue date: 12.Jun.2023

Issue date of this certificate: 12.Jun.2023

Validity of this certificate: 11.Jun.2024

Recertification date: 11.Jun.2026

Certificate No: 23.04.332-MD

General Manager

To verify the validity of this certificate please visit: www.inspect.com.tr

Bu sertifikanın geçerliliğini kontrol etmek için lütfen www.inspect.com.tr'yi ziyaret ediniz

The validity of this certificate is depend on the success of surveillance assessments

Bu belgenin geçerliliği ara denetimlerin başarılı olmasına bağlıdır.

INSPECT Uluslararası Belgelendirme ve Gözetim Hiz. Tic. Ltd. Şti. / TURKEY
www.inspect.com.tr - Belge periyodu 3 yıldır. / Certificate period is 3 years.



100% Hygiene Before and After Injection

Injection

Taking a Blood Sample

Vascular Access



RENASAN® a.ş.
size özel, tek kullanımlık ürünler sunar...

Alcohol Prep Pads