



RENASAN MÜREKKEPLİ ŞERİTLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

Address: Ergazi Mahallesi 1819. Cadde No:3/D Yenimahalle/ANKARA, Turkey

has submitted Declaration of Conformity (Dated: 06/06/2020) according to

CLASS 1 -MEDICAL DEVICES DIRECTIVE 93/42/EEC- 2007/47/EC- Annex IX

(SINIF 1- TIBBI CIHAZLAR DIREKTIFI 93/42/EEC - 2007/47/EC-EK 9)

ISO 13485: 2016 MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM

(ISO 13485:2016 TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ)

Organization has been assessed and found to be conforming with the requirements of the stated directive and standards submitted through Declaration of conformity

Hence manufacturer places the CE marking with his own responsibility as follows:



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- STERIL OLMAYAN)

Product Commercial Brand / Marka: RENASAN Alkollü Swap Mendil

By QSA International, UK

Certification Issue Date: 02 July 2020~ Certification Expiry Date: 01 July 2021

QSA INTERNATIONAL LIMITED

27, Old Gloucester Street, London, WC1N3AX, ENGLAND Startford Ray

Certification Manager

Registration Number: QSA-20072423

Initial Certification Date: 02 July 2020

Certification Expiry Date: 01 July 2023



Email: info@qsai.co.uk
Web:www.qsai.co.uk





28.05.2020

27. 05. 2021

28.05.2021

27, 05, 2022

28, 05, 2022

27.05.2023

Validity of the certificate for the stated period confirms the safety mark. In case the safety mark for the stated period is missing, please verify the validity of the certificate at www.astraia.biz.

ASTRAIA® Certification, s.r.o., Mostná 13, Nitra, Slovakia certification body of management systems hereby issues this

CERTIFICATE

to the company



RENASAN MÜREKKEPLİ ŞERİTLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

Ergazi Mahallesi 1819. Cadde No:3/D Yenimahalle / ANKARA

certification body hereby certifies that the company's

Quality Management System

has been found to be implemented and maintained

in accordance with the requirements set in

ISO 9001:2015

the management system is applicable to:

Manufacturing of Antibacterial,
Disinfectant and Cosmetic Wipes
and Disposable Medical
Products, Restaurant
Consumables and Hygienic
Products

Mr. Daniel Helfer

Certificate No.: QMS-4752-2020 Certificate issued: 28. 05. 2020 Certificate is valid until: 27. 05. 2023



Management System Certification Body No. MSCB-105

CERTIFICATE

No. 20-B-0674 Rev. 0

This is to certify that the Quality Management System of

RENASAN MUREKKEPLI SERITLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

of

Ergazi Mah. 1819.Cadde Teknosite No:3-D Batıkent-Yenimahalle/ANKARA

Company Reg. No.: 7340067418

has implemented and documented a quality management system in compliance with the requirements of the standard

ISO 13485:2016

for

MANUFACTURING AND SALES OF DENTAL BIBS, DENTAL TABLE CLOTHES, ALCOHOL SWAB WIPES

DENTAL HASTA Ö NLÜ ĞÜ , DENTAL TABLA Ö RTÜ SÜ , ALKOLLÜ SWAB MENDIL

The certificate is issued on the basis of the results mentioned in the pertinent audit report. Validity of the certificate is conditionally limited by positive results of surveillance audits, which the certified company committed to undergo.

This certificate can be invalid if the certificate holder does not fulfill the conditions set out in the certification agreement.

Expire date:

Initial issue date:

Jul. 03. 2020 Jul. 02. 2023







G. Gilbert

G. Gilbert

Head of Certification Body





Ergazi Mah. 1819.Cadde No:3-D Teknosite Yenimahalle / ANKARA Tel: 0312 255 60 03 (Pbx) Fax: 0312 255 60 23 website@renasan.com.tr

TECHNICAL DATA SHEET

Product	Renasan Code M0250		
	Product Name Renasan Laminated Cou	ıch Cover Roll	
	Quality Veils Weight per Veil	Descrption Nr. Gr/Mq(+/-0,5)	100% CELLULOSE 1,00 17,00
Raw Material	Quality Micron Corona	Descrption Nr. Gr/Mq(+/-0,5)	-
	Color White grade Whitening method WS Treatment(wet strenght)	Description % (+/-1) Type Yes/No	WHITE 88,00 ECF YES
	Absorption by immersion Klemm method absorption	% (+/-10) mm/10'(+/-5)	468 100
	Longitudinal dry tensile strength. Trasversal dry tensile strenght. Longitudinal wet tensile strength. Trasversal wet tensile strenght.	N/m(+/-50) N/m(+/-50) N/m(+/-30) N/m(+/-30)	477 245 161 84
	Embossing Adhesion Veil Type Suitable Food Contact	Description Type Yes/No	YES POINT POINT SYSTEM YES
Service	Format/Roll width Format Lenght Perforation	cm cm Yes/No	80,00 30,00 YES/ Every 30cm
Rolls	Numenr of tear-off point Roll Lenght Roll width Roll Diameter Labeling Roll packing Packaging Barcode	Nr. m cm cm Description	281,00 200,00 80,00 24,15 Videojet Barcode SHRINK 8022650626074
Вох	Roll box packing Rolls number X boxes number Box Barcode Box measures (LxDxH)	Description nr	BOX 4,00 18025425632541 39x101,5x26,5
Pallet	Pallet type Boxes x Pallet Pallet measures (LxDxH)	Description Nr. cm	EPAL 5 80x120x205 cm

The technical data indicated above are generated from surveys made on articles in our standard range and are provided for information only.

Additional information can be provided upon specific request.

All measures are subject to tolerance by law.