SZUTEST

CERTİFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 333410054

YÜCEL MEDİKAL VE TEKSTİL ÜRÜNLERİ SAN. TİC. LTD. ŞTİ.

Selahaddin Eyyubi Mah. 1612. Sok. No:19 Esenyurt, İstanbul, TÜRKİYE

EN ISO 13485:2016

Design, Production and Sales of Absorbable Haemostatic Gelatin Sponge, Bone Wax and Oxidised Regenerated Cellulose

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	30.11.2010
Issue Date	19.10.2022
Expiry Date	18.10.2025
Revision Date/No	19.10.2022 / 5

TÜRKAK BDS NO YS-FB13-3B58

TÜRKAK

AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.

EC Certificate
Full Quality Assurance System

Certificate No.:
12853-2018-CE-ARE-NA-PS

Project No.:
PRJC-572112-2017-PRC-ARE

Valid Until:
02 August 2023

This is to certify that the quality system of:

Yücel Medikal
ve Tekstil Ürünleri san.Tic.Ltd.Şti.
Selahaddin Eyyubi Mah.1612 Sok.No:19 34850 Esenyurt, Istanbul, Turkey

For design, production and final product inspection/testing of:

Sterile Absorbale Haemostatic Gelatin Sponge

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 02 August 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Sholeh Gheissar

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **12853-2018-CE-ARE-NA-PS**

Project No.: **PRJC-572112-2017-PRC-ARE**

Valid Until: **02 August 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	**2018-08-02**

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Absorbale Haemostatic Gelatin Sponge	**CLINISPONGE Absorbale Haemostatic Gelatin Sponge** Standart 80x50x10 mm / Dial 30x30x10 mm Standart 70x50x10 mm / Tampon 80x Ø 30 mm Special 80x50x1mm / Dental 10x10x10 mm Special 70x50x1 mm / Dental 14x7x7 mm Film 200x70x0.5 mm / Powder 1 gr	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 12854-2018-CE-ARE-NA-PS

Sites covered by this certificate

Site Name	Address
Yücel Medikal	Selahaddin Eyyubi Mah.1612 Sok.No:19 34850 Esenyurt, Istanbul, Turkey

EU Representative

Yuecel Senol, Simmeringer Haupt Str. 81/1/6 1110, Vienna, Austria

Terms and conditions

EC Certificate
Full Quality Assurance System

Certificate No.: **12853-2018-CE-ARE-NA-PS**

Project No.: **PRJC-572112-2017-PRC-ARE**

Valid Until: **02 August 2023**

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate