



Certificate

ISO 9001 : 2015

**DETRO HEALTHCARE KİMYA
SANAYİ A.Ş.**

Atatürk Mah. Adnan Menderes Cad. No:7 Esenyurt İstanbul/ TURKEY

This certificate shows that the quality management system of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria.

SCOPE

MEDICAL HYGIENE PRODUCTS, MEDICAL DISINFECTANTS, HOSPITAL HYGIENE PRODUCTS, HOSPITAL DISINFECTANTS, MEDICAL DEVICE AND EQUIPMENT DISINFECTANTS, ULTRASONIC WASHERS, ENDOSCOPE WASHER AND DISINFECTOR, MEDICAL DEVICE CLEANING AND MAINTENANCE PRODUCTS, AUTOMATIC PULVERIZATION MACHINE AND SOLUTIONS, AIR STERILIZER, VETERINARY HYGIENE PRODUCTS, VETERINARY DISINFECTANTS, ANTISEPTICS, BIOCIDAL PRODUCTS, ANTIBACTERIAL HAND SOAPS, HAND AND SKIN DISINFECTANTS, NATURAL HYGIENE PRODUCTS, SOAP, DETERGENTS, GENERAL CLEANING PRODUCTS, LUBRICANTS, BOILER CHEMICALS, TECHNICAL MAINTENANCE CHEMICALS, POOL CHEMICALS, CHEMICAL MATERIALS, AGRICULTURAL SOIL SUPPORTIVE PRODUCTS PRODUCTION AND SALE

Certificate No : KY-25923
Registration Date : 11.09.2018
Reissue Date :
Expiry Date : 10.09.2019
Certificate Period : 3 Years (From the date of registration)



ACCREDITED

Management
Systems
Certification Body

MSCB-109

PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL
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FR.86 Rev.3

CERTIFICATE



Medical Devices Quality Management System
CERTIFICATE NO: 31732601

Detro Healthcare Kimya Sanayi A.Ş.

Atatürk Mah. Adnan Menderes Cad. No:7 Esenyurt, İstanbul, Türkiye

EN ISO 13485:2016

**Design, Production, Sales and Technical Service of Medical Device
Disinfectant, Endoscope Washer and Disinfector Device**

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

Issue Date 22.11.2017
Expiry Date 21.11.2020
Revision Date/No 24.12.2018 / 1



TÜRKAK BDS NO
YS-36BA-A1B5



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>.



CERTIFICATE

DETRO HEALTHCARE KİMYA SANAYİ A.Ş.
ATATÜRK MAH. ADNAN MENDERES CAD. NO:7 ESENYURT / İSTANBUL / TURKEY

is audited by İNTERSİSTEM TEKNİK BELGELENDİRME Certification and applied
Cosmetic Quality Management System & Good Manufacturing Practices System meet the requirements of

G M P - ISO 22716:2007

standard for the following activities.

MEDICAL HYGIENE PRODUCTS, MEDICAL DISINFECTANTS, HOSPITAL HYGIENE PRODUCTS, HOSPITAL DISINFECTANTS, MEDICAL DEVICE AND EQUIPMENT DISINFECTANTS, ULTRASONIC WASHERS, ENDOSCOPE WASHER AND DISINFECTOR, MEDICAL DEVICE CLEANING AND MAINTENANCE PRODUCTS, AUTOMATIC PULVERIZATION MACHINE AND SOLUTIONS, AIR STERILIZER, VETERINARY HYGIENE PRODUCTS, VETERINARY DISINFECTANTS, ANTISEPTICS, BIOCIDAL PRODUCTS, ANTIBACTERIAL HAND SOAPS, HAND AND SKIN DISINFECTANTS, NATURAL HYGIENE PRODUCTS, SOAP, DETERGENTS, GENERAL CLEANING PRODUCTS, LUBRICANTS, BOILER CHEMICALS, TECHNICAL MAINTENANCE CHEMICALS, POOL CHEMICALS, CHEMICAL MATERIALS, AGRICULTURAL SOIL SUPPORTIVE PRODUCTS

Certificate No : GM-0090- 120052-TR

08.08.2017

Certificate Date

13.09.2018

Certificate Last Issue Date

07.08.2020

Certification Period Expiration Date

07.09.2019

Certificate Expiry Date



FR.BEL.81 Yayın Tarihi:01.07.2013 Rev.No:03 Rev.Tarihi:08.05.2015

Rev:01 / Revizyon Tarihi:10.09.2018

Bu belge, Müşterinin ISQ'nun kurallarına ve sözleşme şartlarına uyduğu sürece geçerlidir. Sertifika geçerlilik durumu ISQ internet sitesinden takip edilebilir.

İNTERSİSTEM TEKNİK SERTİFİKASYON UZULSARARASI BELGELENDİRME DEN. GÖZ. ve EĞİT. HİZM. SAN. ve TİC. LTD. ŞTİ.

Hells Beyaz Ofis Yeşilbağlar Mah. Selvili Sk. No: 2 B Blok Kat: 3 BÜro 316 Tel: 0216 305 46 99 - 0216 305 46 66 Pendik - İstanbul - Türkiye

e-mail: info@intersistemteknik.com - www.intersistemteknik.com

EC CERTIFICATE AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices
93/42/AT Tıbbi Cihaz Yönetmeliği Ek II'ye göre

Full Quality Assurance System
Tam Kalite Güvencesi

Certificate Number: 2195-MED-1118102
Sertifika Numarası

Manufacturer: Detro Healthcare Kimya Sanayi A.Ş.
Üretici Atatürk Mah. Adnan Menderes Cad. No:7 Esenyurt, İstanbul / TÜRKİYE

Product(s): (1) Endoscope Washer and Disinfector Device
Ürün(ler) (1) Endoskop Yıkayıcı ve Dezenfektör Cihazı
(2) Medical Device Disinfectants
(2) Tıbbi Cihaz Dezenfektanları

Model(s): (1) DETROWASH-(5001, 5002, 5003, 5004, 5005, 6001, 6002, 6003, 6004, 6005, 7001,
Model(ler) 7002, 7003, 7004, 7005, 8001, 8002, 8003, 8004, 8005)
(2) DETRO PLUS OPA, DETRO FORTE, DETRO OPA, DETRO PLUS, DETROSEPT AF,
STR DIS 1005, STR SP 5001, STR DIS 1011, STR DIS 1012, STR DIS 1004, SEMILAC,
AKADENT, AKADENT READY, DETROCID ENZYM, AKADENT EXTRA, DETROSAN AF,
DETRO ACTIV, DETRO CID ACTIV, AKASPRAY

Reference Report No: MM0135-P010-R01, MM0135-P010-R02, MM0135-P010-R03, MM0135-P010-R04,
Referans Rapor No MM0135-P012-R01

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II (madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğinin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir. Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır.

This EC certificate is valid till 2024-04-28.
Bu AT Sertifikası 2024-04-28 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi: 2011-06-30
Revision No./ Revizyon No.: 08 Recertification/Yeniden Belgelendirme
Revision Date/ Revizyon Tarihi: 2019-04-29

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı