PCA

PARTNERS CERTIFICATE ASSURANCE

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)

IAS ACCREDITED

Management Systems Certification Body

MSCB-103

PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49
www.pca-tr.com info@pca-tr.com

FR.86 Rev.3

Digitally signed by Iurcu Nicolae
Date: 2019.11.06 01:50:49 EET
Reason: MoldSign Signature
Location: Moldova

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31732601

Detro Healtcare 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

TÜRKAK
Tıbbi Cihazlar K. Y. S.
TS EN ISO/IEC 17021
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.

ISQ Certification Body

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	13.09.2018
Certificate Date	Certificate Last Issue Date
07.08.2020	07.09.2019
Certification Period Expiration Date	Certificate Expiry Date

ISQ GMP GOOD MANUFACTURING PRACTICE

İNTERSİSTEM SERTİFİKASYON SAN. VE TİC. ŞTİ. APPROVAL 2007

ÖSAS ÖSTERREICH Spezielle Akkreditierung Service EN ISO/IEC 17021 ACCREDITED Ö-018 austria

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

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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: *Üretici*	**Detro Healthcare Kimya Sanayi A.Ş.** Atatürk Mah. Adnan Menderes Cad. No:7 Esenyurt, İstanbul / TÜRKİYE
Product(s): *Ürün(ler)*	**(1) Endoscope Washer and Disinfector Device** *(1) Endoskop Yıkayıcı ve Dezenfektör Cihazı* **(2) Medical Device Disinfectants** *(2) Tıbbi Cihaz Dezenfektanları*
Model(s): *Model(ler)*	(1) DETROWASH-(5001, 5002, 5003, 5004, 5005, 6001, 6002, 6003, 6004, 6005, 7001, 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: *Referans Rapor No*	MM0135-P010-R01, MM0135-P010-R02, MM0135-P010-R03, MM0135-P010-R04, 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 yönetmeliğin 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

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
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