SZUTEST

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.
Head Office/Merkez: Atatürk Mah. Cemal Gürsel Cad. No:8 Esenyurt, İstanbul, TÜRKİYE
Branch Office/Şube: 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)*
Product specifications are stated on the following page(s).
Ürün detayları ilerleyen sayfa(lar)da verilmiştir.

Reference Report No: *Referans Rapor No*
MM0135-P010-R01, MM0135-P010-R02, MM0135-P010-R03, MM0135-P010-R04, MM0135-P012-R01, MM0135-P014-R01, MM0135-P015-R01, MM0135-P016-R01, MM0135-P016-R04, MM0135-P016-R05, MM0135-P018-R01, MM0135-P018-R02, MM0135-P019-R01, MM0135-P019-R02, MM0135-P019-R03

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). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

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. Steril kondisyondaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla limitlidir. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla limitlidir.

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.:* 13 Rev./*Rev.*
Revision Date/ *Revizyon Tarihi:* 2021-05-20

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

This version of certificate has come into force on 23.03.2017 / Bu sertifika versiyonu 23.03.2017 tarihinde yürürlüğe girmiştir. U2 2195-MED-1118102 Rev.13

Certificate Number: 2195-MED-1118102
Sertifika Numarası

Product Specifications:
Ürün Detayları:

Product Name	**Model Name**
(1) Endoscope Washer and Disinfector Device *(1) Endoskop Yıkayıcı ve Dezenfektör Cihazı*	DETROWASH-(5001, 5002, 5003, 5004, 5005, 6001, 6002, 6003, 6004, 6005, 7001, 7002, 7003, 7004, 7005, 8001, 8002, 8003, 8004, 8005)
(2) Medical Device Disinfectants *(2) Tıbbi Cihaz Dezenfektanları*	DETRO OPA, DETRO PLUS OPA, DETRO PLUS, DETRO FORTE, 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, DETROSAN SFC, AKASPRAY TÜCHER, DETRO PAA 1500, DETRO PAA 2200, DETRO PLUS PAA, DETRO PLUS PAA DW, DETRO HEMOPLUS, DETRO HEMOPLUS PAA, DETRO SPRAY, DETROSAN HP SPRAY, DETROSAN AF WIPES, VELO ALCOHOL WIPES, DETROSAN HP WIPES

NOTIFIED BODY CONFIRMATION LETTER
No: MD0039-CL-01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 and implementing Regulation (EU) 2023/1194 amending implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain medical devices.

This letter confirms that **SZUTEST Konformitätsbewertungsstelle GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2975** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name	DETRO HEALTHCARE KİMYA SANAYİ A.Ş.
Address	Atatürk Mah. Cemal Gürsel Cad. No:8 Esenyurt, İstanbul, TÜRKİYE
SRN Number (if available)	TR-MF-000022410

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded, and for which the SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but SZUTEST Konformitätsbewertungsstelle GmbH has not yet taken responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance with the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR
- 31 December 2028 for Annex XVI products which do not require a clinical investigation.
- 31 December 2029 for Annex XVI products which require a clinical investigation.

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

MEHMET IŞIKLAR
General Manager

SZUTEST
Konformitätsbewertungsstelle GmbH
Friedrich-Ebert-Anlage 36
60325 Frankfurt am Main
USt-IdNr. DE815819575
info@szutest-germany.de

SZUTEST Konformitätsbewertungsstelle GmbH-NB 2975
Friedrich-Ebert-Anlage 36 D-60325 Frankfurt am Main /GERMANY

To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

Table 1: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (Under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	*N/A*	*N/A*	N/A

Table 2: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (Under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Endoscope Washer and Disinfector Device DW-5001 STR-5001 DW-6001 DW-6002 DW-6003 DW-6004 DW-8001 DW-8002 DW-8003 DW-8004 DW-5002 DW-5003 STR-5003 DW-5004 DW-5005 DW-6005 DW-7001 STR-7001 DW-7002 DW-7003 STR-7003 DW-7004 DW-7005 DW-8005	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro OPA (Orthophthalaldehyde)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Plus OPA (Orthophthalaldehyde)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.

To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31732601

DETRO HEALTHCARE KİMYA SANAYİ A.Ş.

Atatürk Mah. Cemal Gürsel Cad. No:8 Esenyurt, İstanbul, TÜRKİYE

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.

First Issue Date	22.11.2017
Issue Date	16.11.2023
Expiry Date	15.11.2026
Revision Date/No	16.11.2023 / 7

TÜRKAK BDS NO YS-E4C2-2F49

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.

SZUTEST

SERTİFİKA

Medikal Cihazlar Kalite Yönetim Sistemi

SERTİFİKA NO: 31732601

DETRO HEALTHCARE KİMYA SANAYİ A.Ş.

Atatürk Mah. Cemal Gürsel Cad. No:8 Esenyurt, İstanbul, TÜRKİYE

EN ISO 13485:2016

Tıbbi Cihaz Dezenfektanı, Endoskop Yıkayıcı ve Dezenfektör Cihazı Tasarımı, Üretimi, Satışı ve Teknik Servis Faaliyetleri

Medikal Cihazlar Kalite Yönetim Sistemine yukarıda belirtilen kapsam dahilinde sahip olduğunu onaylar.

İlk Yayın Tarihi	22.11.2017
Yayın Tarihi	16.11.2023
Geçerlilik Tarihi	15.11.2026
Revizyon Tarih/No	16.11.2023 / 7

TÜRKAK BDS NO YS-E402-2849

TÜRKAK AB-0044-YS

Genel Müdür Yardımcısı

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