

# 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 sınırlıdır. Ölçüm fonksiyonlu sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla sınırlıdır.

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

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

# SZUTEST

**Certificate Number: 2195-MED-1118102**  
Sertifika Numarası

**Product Specifications:**  
Ürün Detayları:

Product Name	Model Name
<b>(1) Endoscope Washer and Disinfector Device</b> (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)
<b>(2) Medical Device Disinfectants</b> (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

This version of certificate has come into force on 23.08.2017. Bu sertifika versiyonunun 23.08.2017 tarihinde yürürlüğe girdiği belirtilmiştir. 2195-MED-1118102 Rev.19

# 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



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 UYGUNLUK DEĞERLENDİRME A.Ş.**

Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

[Szutest.com.tr](http://Szutest.com.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



Genel Müdür Yardımcısı

Bu belgenin doğrulanması belge üzerinde bulunan karekodların mobil cihazlara okutulması, <http://public.szutest.com.tr> adresinde gerekli bilgilerin girilmesi veya BDS no kullanılarak <https://tbds.turkak.org.tr> adresinden gerçekleştirilebilir.

## **DECLARATION OF CONFORMITY**

02.08.2023

**Products Name:** Detro Enzym, Detro Enzym Plus DW, Detro Matic Enzym, Detro Matic A, Detro Matic NF, Detro Matic NS, Detro Enzym Foam, Detro Lube, Detro Lube Spray, Detro Multicare, Detro Multicare R, Detro Dent, Detro Dent R, Detro Instruclean, Detro Forte test strip, Detro OPA test strip, Detro PAA 1500 test strip, Detro PAA 2200 test strip, Detro Activ test strip, Detrocid Enzym test strip, Detrocid Activ test strip, Akadent Extra test strip, Detro Cleanex, Basins, Detro vericheck, Akadent Ready test strip

**Producer Name:** Detro Healthcare Kimya Sanayi A.Ş.

**Producer Address:** Atatürk mh. Cemal Gürsel cd. No:8/3 Esenyurt-İstanbul/Turkey

**Class:** Class I

We declare that above written Class I products are produced in accordance with 93/42 EEC Full Quality Assurance System / Annex 7.

Şevket KILIÇ

**General Manager**

  
**detrox**<sup>®</sup>  
DETRO HEALTHCARE KİMYA SANAYİ A.Ş.  
Atatürk Mahallesi, Cemal Gürsel Caddesi  
No:8/3 Esenyurt - İSTANBUL Tel: 0 212 659 77 62  
Fax: 0 212 659 77 63 - Esenyurt Y.D. 293 050 8762

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

Atatürk mh. Cemal Gürsel cd. No:8/3 Esenyurt-İstanbul/Turkiye

Tel. +90 212 659 77 60 Fax +90 212 659 77 63

✉ info@detrox.com.tr - www.detrox.com.tr

“Pursuant to the provisions of Regulation (EU) No. 2023/607 issued by the European Commission, devices regulated in accordance with Directive 93/42/EEC, provided that they fulfill the conditions specified in this Regulation:

- December 31, 2027 for class III devices and class IIb implantable devices excluding sutures, staples, dental fillings, dental brackets, dental crowns, screws, wedges, plates, wires, pins, clips and connectors;
- December 31, 2028 for class IIb devices other than those covered above, class IIa devices and class I devices placed on the market in sterile condition or with a measuring function
- Devices for which the conformity assessment procedure under Directive 93/42/EEC does not require the involvement of a notified body, for which a declaration of conformity was issued before 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body 31 December 2028

until the dates of 2017/745 EU Medical Device Regulation.

Within the scope of Announcement No. 2023/KK-5 on the Implementation of the Provisions of Regulation (EU) No. 2023/607, our company has signed the official contract with SZUTEST GMBH Notified Body in order to carry out the certification process in accordance with the 2017/745 EU Medical Device Regulation in force and our review processes have been initiated. At the same time, an MDD Surveillance Audit contract was signed with SZUTEST Conformity Assessment Inc. Notified Body in order to extend our MDD Certificate, which will expire on 26.05.2024, until 26.09.2024 in accordance with the 93/42/AT Medical Device Directive.

After the application made to the Competent Authority within the scope of Announcement No. 2023/KK-5, our MDR Transition Period Extension process has been approved and the attached cover letter has been received.”

**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:

<b>Company Name</b>	DETRO HEALTHCARE KİMYA SANAYİ A.Ş.
<b>Address</b>	Atatürk Mah. Cemal Gürsel Cad. No:8 Esenyurt, İstanbul, TÜRKİYE
<b>SRN Number (if available)</b>	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 İŞIKLAR**  
General Manager



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



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**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



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**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 Expiry 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 Expiry 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 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.



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Detro Plus (Glutaraldehyde)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Forte (Glutaraldehyde)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detrocid Endo (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Akadent (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detrocid Endo Ready (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Akadent Ready (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Akadent Extra (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.



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Detrocid Enzyme (Alkylamine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro PAA 1500 (1500 ppm peracetic acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro PAA 2200 (2200 ppm peracetic acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Plus PAA (15% Peracetic Acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Plus PAA DW (15% Peracetic Acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Activ (%0,16 Perasetik Asit (1600 ppm))	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Cid Activ (%0,16 Perasetik Asit (1600 ppm))	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expiry Date: 28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.



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Detro Hemoplus (Citric Acid, Malic Acid, Lactic Acid)	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 Hemoplus PAA (Peractic Acid)	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.
Detrosept AF (Alcohol (30%) + QAC)	Class IIa	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 San AF (Alkyl Amine + QAC)	Class IIa	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.
Akaspray (Alcohol (60%) + QAC)	Class IIa	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.
Detrosan SFC (Alkyl Amine + QAC)	Class IIa	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 Spray (Alcohol (50%) + QAC)	Class IIa	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.



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Detrosan HP Spray (Hydrogen Peroxide + Salicylic Acid)	Class IIa	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.
Akaspray Tücher (Alcohol (60%) + QAC +Handkerchief Product Solutionimpregnated wipes)	Class IIa	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 San AF Wipes (Alkyl Amine + QAC+ Wipes Product: Solution Impregnated Wipes)	Class IIa	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 San HP Wipes (Hydrogen Peroxide + Salicylic Acid + Wipes Product: Solution Impregnated Wipes)	Class IIa	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.

### Confirmation Letter Revision History

Date	Version of the letter	Action
2024/03/08	MD0039-CL-01	Initial issue



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DETRO HEALTHCARE KİMYA SANAYİ A.Ş.

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

Ref. :

Tarih/Date : 08.03.2024

Konu/Subject : 93/42/EEC Gözetim Denetimi Hk.

İlgili makama,

Aşağıda bilgileri yer alan firmanın 93/42/EEC sertifikalarına ait yıllık gözetim denetimi sorumluluğu, firmanın (EU) 2017/745 kapsamında yetkili bir onaylanmış kuruluşa başvurmaması durumunda sertifika geçerlilik tarihine kadar, 26.05.2024 tarihine kadar (EU) 2017/745 kapsamında yetkili bir onaylanmış kuruluşa başvurması ve 26.09.2024 tarihine kadar (EU) 2017/745 kapsamında yetkili bir onaylanmış kuruluşa sözleşme imzalaması durumunda (EU) 2023/607 yönetmeliği 1. maddesinin 3e paragrafı kapsamında 26.09.2024 tarihine kadar SZUTEST Uygunluk Değerlendirme A.Ş. tarafından yürütülecektir.

Firma Adı: DETRO HEALTHCARE KİMYA SANAYİ A.Ş.

Ürünler:

1. Endoskop Yıkayıcı ve Dezenfektör Cihazı

Sertifika#1: 2195-MED-1118102

Revizyon No:13

Revizyon Tarihi: 20.05.2021

Yayın Tarihi: 30.06.2011

Geçerlilik Tarihi: 28.04.2024

2. Tıbbi Cihaz Dezenfektanları

Sertifika#1: 2195-MED-1118102

Revizyon No:13

Revizyon Tarihi: 20.05.2021

Yayın Tarihi: 30.06.2011

Geçerlilik Tarihi: 28.04.2024

Bilgilerinize arz ederim.

Saygılarımla.



Hasan Akkök

Yetkili Otorite İletişim ve Komite Koordinatörü