CYW-S601

www.choyangmed.com

The Reliable Solution for Endoscope Reprocessing

CMI CHOYANG MEDICAL INDUSTRY

CHOYANG MEDICAL INDUSTRY

SAFE ENDOSCOPE FOR ALL

CYW-S601 is the newest endoscope washer-disinfector of Chaoyang Medical Industry Ltd., which has strictly applied the highest international standards for infection control of medical device.

An important premise for the safest and most reliable cross-infection prevention during endoscope reprocessing is not to reuse all instruments and chemical products used in reprocessing.

CYW-S601 is compatible with disposable disinfectant only and has a more hygienic and safe endoscope reprocessing capability.

CYW-S601 is a higher grade endoscope washer-disinfector applied the latest monitoring system and program, as well as various washing and disinfection functions.

Safe and effective performance

- Strong cleaning power using rotating impeller
- Proved disinfection effect with single shot disinfectant
- Confidence in prevention of infection and safety

Reliable Process

- Real-time leakage test
- Individual monitoring of endoscope channels
- Data management of full endoscope reprocessing

Various functions of advanced technology

- Filtered water and air supplied to equipment
- Detergent and alcohol flushing function
- Self-disinfection, barcode system and Printer

User-friendly design

- Intuitive and easy-to-handle touch screen
- Convenient replacement of disinfectant, detergent and alcohol
- Hands-Free Operation

CYW-S601

The Reliable Solution for Endoscope Reprocessing

01

AUTOMATED TOP COVER OPENING SYSTEM

02

7" WIDE TFT LCD TOUCH SCREEN WITH USER-FRIENDLY OPERATING SYSTEM

03

ADVANCED WATER FILTRATION SYSTEM WITH STANDARD BACTERIA RETENTION MICRON(0.2um) WATER FILTER

04

SINGLE SHOT HIGH LEVEL DISINFECTANT WITH ACCURATE DILUTION AMOUNT CONTROL

05

HANDS-FREE LID OPERATION WITH EASY TO USE FOOT SWITCH TO PREVENT CROSS-CONTAMINATION

08

SPRAY ARM LOCATED AT TOP COVER FOR DYNAMIC WASHING

07

CONTINUOUS CHANNEL MONITORING WITH FLOW SENSORS AND LEAKAGE MONITORING BY DIFFERNTIAL PRESSURE DETECTION

06

PROCESS DATA IS SAVED WITH REPROCESSING OPERATOR AND PATIENT CODE BY BARCODE READING SYSTEM

CE 1639

VALIDATED PROCESS

It fundamentally solved problems of contamination and degradation of disinfection performance of reusable disinfectants by using a single shot disinfectant.

A cartridge system minimizes user exposure to irritating disinfectants and conveniently replaces disinfectant container from the front.

Maximum 6 endoscope channel connection ports are applicable to any type of endoscope for real-time monitoring function of each channel.

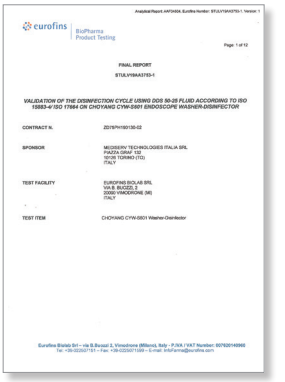
Real-time leakage monitoring function that guarantees safety of the endoscope even during washing and disinfection process.

LCD touch screen that allows you to check all progress in real time and simple operation that is executed with one touch, and you can change each process.

Certificate

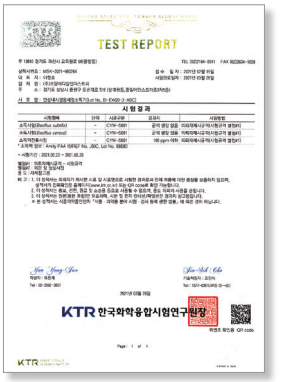
ISO 15883 – 1 & 4 COMPLIANT

CYW-S601 has been certified to ISO 15883-1 & 4, which is an individual certification standard for endoscope washing and disinfection and is the best product that has proven its ability and trust in endoscope reprocessing



FINAL REPORT

VALIDATION OF THE DISINFECTION CYCLE USING DOS 50-25 FLUID ACCORDING TO ISO 15883-4/ ISO 17664 ON CHOYANG CYW-S601 ENDOSCOPE WASHER-DISINFECTOR



TEST REPORT

KTR 한국화학융합시험연구원장

CHEMICAL SOLUTIONS

CHOYANG PAA 15

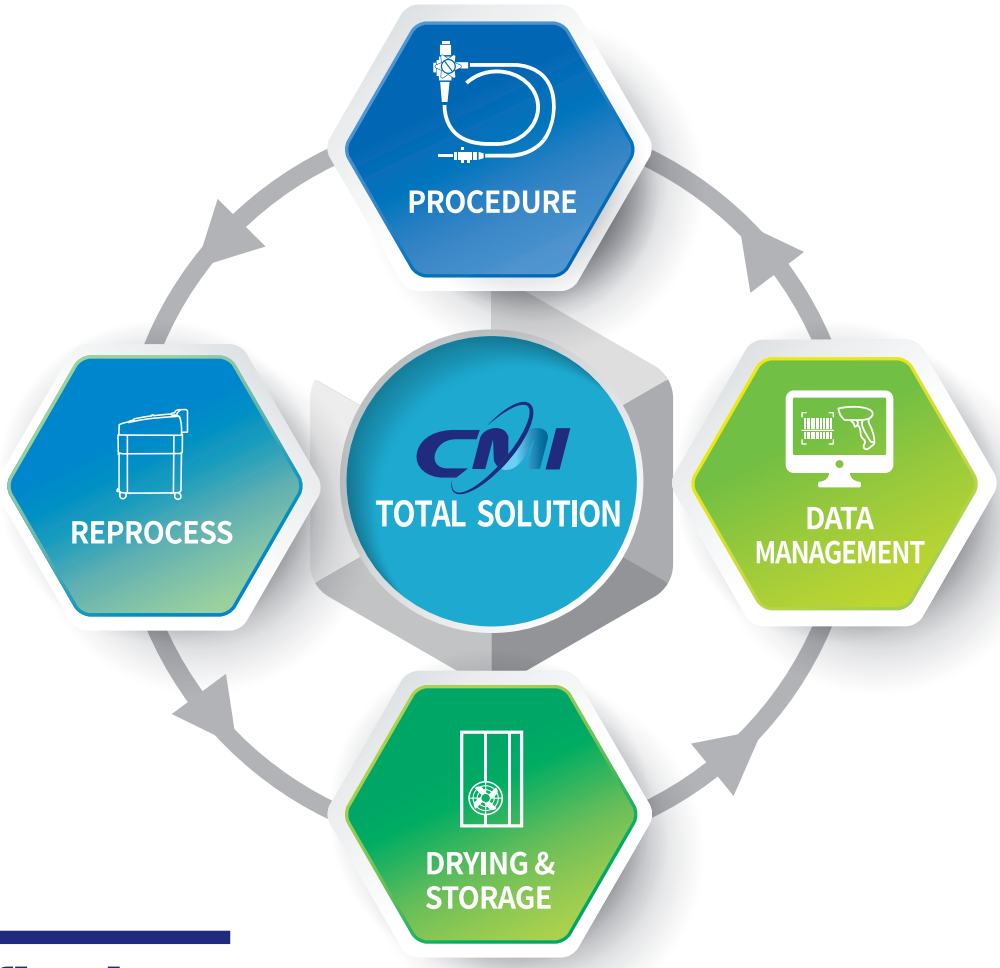
- Single-shot disinfectant for endoscope washer CYW-S601.
- Excellent performance verification with highly concentrated Peracetic Acid in CYW-S601.
- CHOYANG PAA15 has the highest levels of disinfection capacity, safety and effectiveness.

CHOYANG VIRUZYME®

- Viruzyme® is a biological cleaner using five enzymes that is designed for decontamination of medical, surgical, dental and endoscopic instruments.
- Viruzyme® is particularly effective for removing high levels of proteins, fats and organic contaminants from surfaces, including dried on blood and tissue.

TOTAL SOLUTION

CMI provides a total solution for flexible endoscope reprocessing



Specifications

Leakage	Real time & Manual Range : 180mbar~300mbar
Channel Monitoring	6hannel flow monitoring in all processes
Display	7"wide TFT LCD with touch control
Basin Capacity	8Liter
Tank Capacity	Alcohol / Detergent : 1 Liter
Water Filter	Pre-filter Carbon filter Micron Filter(0.2㎛)
Interface	Barcode reading system
Operation	Automatic Prcedure by DB system Print out all Processing steps and record in DB system
Temperature Control	Heater for disinfectant(Max. 60°C)
Couplers	1 outlet for leakage test and 6 outlets for disinfection
Electrical Requirements	220~240 VAC, 50~60Hz
Dimensions	850 X 550 X 1080mm(W X D X H)
Weight	80Kg

CHOYANG
MEDICAL INDUSTRY

More than 25 years experience in Endoscope Reprocessing

CE
1639

http://www.choyangmed.com

CHOYANG MEDICAL INDUSTRY LTD.

5FL., JOONGIL EINES PLATZ III, 519, DUNCHON-DAERO,
JUNGWONG-GU, SEONGNAM-SI, GYEONGGI-DO 13216, KOREA
Tel: +82-31-747-9900 **E-mail**: choyang@choyangmed.com

EC Certificate Full Quality Assurance System: Certificate KR19/81826265

The management system of

Choyang Medical Industry Ltd.

5Fl, Joongil Eines Platz III, 519, Dunchon-daero, Jungwon-gu
Seongnam-si, Gyeonggi-do, 462-807, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Endoscope Washer-Disinfectors (Model : CYW-100, CYW-201, CYW-501, CYW-DUO, CYCLEAN, CYW-S601);

CO2 Surgical Laser for removal of malignant lesions, tumors and acne scars. (Model : Cosmopulse 25, Cosmopulse II, Cohlus);

Q-Switched Nd:Yag Laser for the treatment of Keloids and Hypertrophic scars, Atrophic facial acne scars (Model: Genesis-Q)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 19 September 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 19 September 2008
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered KR/SEL Y-PC/14373

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Certificate KR14/02221

The management system of

Choyang Medical Industry Ltd.

5Fl, Joongil Eines Platz III, 519, Dunchon-daero, Jungwon-gu,
Seongnam-si, Gyeonggi-do, 462-807, Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture, Installation and Servicing of Endoscope Washer-Disinfectors, CO2 Surgical Lasers and Q-Switched Nd:Yag Laser.

This certificate is valid from 19 September 2020 until 19 September 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 September 2023
Issue 8. Certified since 19 September 2008

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Dear Manufacturers,

As you may already know, the EU parliament voted last week in favour of extending the deadlines of the MDR (EU) 2017/745 transition. This decision was mainly taken to avoid any medical device shortage on the European Market.

The approved text is granting an automatic extension of the MDD certificate validity till 31st December 2027 for Class III & Class IIb implantable devices and 31st December 2028 for other devices.
However, the following conditions are to be met:

1. Devices continue to comply with MDD
2. There are no significant changes in design and intended purpose
3. The devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, nor to other aspects of the protection of public health
4. Manufacturers must have a quality management system compliant with MDR (EU) 2017/745 article 10(9) before 26 May 2024
5. Manufacturers or their authorized representatives has lodged a formal application with a notified body before 26 May 2024 and signed a contract covering devices for transition before 26 September 2024 for the devices covered within the MDD certificate.

For MDD certificates that have already expired, the aforementioned condition 5 is replaced by either having a contract signed for MDR with a Notified body or having a derogation issued by a European competent authority before certificate has expired.

The voted text is emphasizing that appropriate surveillance activity for the maintenance of the MDD certificate shall be conducted by the Notified Body having issued the MDD certificate except if an agreement is put in place with the Notified body in charge of MDR conformity assessment. In SGS, we will conduct at least systematic regular on-site surveillance to maintain issued MDD certificate. We will continue conducting technical file reviews on a sampling basis for Class IIa and IIb products over the transition period. In addition, based on future guidance received from the commission or our risk assessment we may include partial assessment of Class III devices as well within this period. To allow the above, we need to establish a new contract and associated proposal with you if you wish to extend the validity of your MDD certificate within the transition period. Please note that the validity of the current certificate is extended and that NO new certificate will be issued as it is against the law.

As the conditions are determined based on lodging an MDR application and signing an MDR contract with a Notified Body, we are strongly encouraging you to contact your local medical device office to initiate the process of MDR conformity assessment as soon as possible to avoid last minute rush. We shall manage start of transition to MDR of all our MDD certified manufacturers in the next 18 months, and while the time is limited, we will do our best to support you transition within your defined timelines.

However, since signing contract can take up in between 2 to 6 months, we would require those who wish to go through this process to submit application to us as soon as possible.

For any further question, please contact your local medical device office.

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Detro® Enzym Plus

Enzymatic Cleaner for Medical Instruments and Endoscopes

Detro® Enzym Plus DW

Enzymatic Cleaner for Medical Instruments and Endoscopes

PRODUCT PROPERTIES:

- Concentrated product.
- Reduces microbial load of instruments by cleaning organic soil.
- Reduces corrosion risk of instruments by cleanig inorganic soil.
- Thanks to its 4 enzyme content, it removes residues on the instruments and provides more effective cleaning.
- Contains corrosion inhibitor.

COMPOSITION:

- Enzymes (amilase, protease, lipase, cellulase), glycol, noniyonic surfactant, anticorrosive materials

USAGE AREAS:

- Provides pre-cleaning for medical devices and edoscopes and all kinds of surgical instruments. Cleans the organic contaminations like blood, oil, protein, starch on surfaces. Solves remnants on instruments thanks to enzymes and so, it provides more effective cleaning. It is compatible with matierials like glass, rubber, wood, ceramic, silicone, plastic and stainless steel.

USAGE:

- It is suitable for use in ultrasonic washing machines and manually.
- The product is used by diluting at %0,5 (5ml to 1L water) concentration.
- Effective in 5 minutes in ultrasonic or manuel usage.
- Solution life is 24 hours.
- At the end of cleaning the instruments are rinsed thoroughly.

PACKAGE :

QUANTITY	PACKING TYPE	BARCODE	CATALOG CODE
5L	4 x DRUM	8680097103499	S-M.DET.3.0020

USAGE AREAS:

- It is used for pre-cleaning of flexible endoscopes in Detrowash series endoscope washing and disinfection devices. It cleans the residues such as blood, oil, protein, starch on the surface of the endoscope.
- It does not harm plastic, silicon, glass, acrylate, rubber and rubber materials.

USAGE:

- Designed to be used with Detrowash series.
- Place the drum in the concentrated cleaner compartment in the device.
- Place the concentrated celaner inlet of the device into the drum.
- The solution is automatically diluted and used.

PACKAGE :

QUANTITY	PACKING TYPE	BARCODE	CATALOG CODE
5L	4 x DRUM	8680097104236	S-M.DET.3.0026

Detro® Plus PAA

Peracetic Acid Based High Level Medical Instrument and Endoscope Disinfectant

Detro® Plus PAA DW

Peracetic Acid Based High Level Medical Instrument and Endoscope Disinfectant

PRODUCT PROPERTIES:

- Concentrated product
- Provides high level disinfection.
- Aldehyde and phenol free
- Class II B product, according to directive 93/42/EEC.

COMPOSITION :

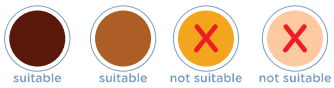
- %15 peracetic acid, auxiliary agents.

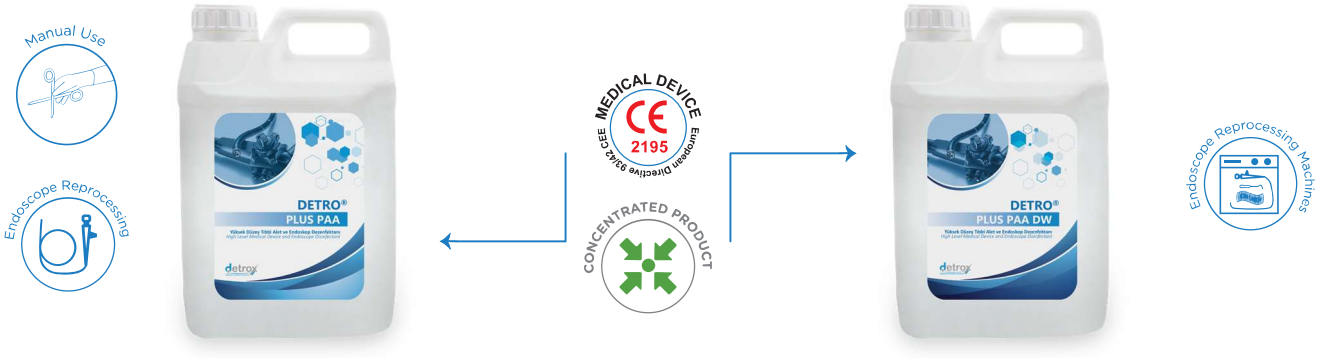
MICROBIOLOGICAL ACTIVITY :

- Bactericidal, fungicidal, tuberculocidal, virucidal, sporicidal in 5 minutes

Test Strips

These are the test strips used to monitor the peracetic acid content in the solution. If the strips give any of the valid colors, the solution is active.





USAGE AREAS:

- Used for high-level disinfection of general surgery, anesthesia and dental surgical instruments made of stainless steel, rigid and flexible endoscopes, medical instruments made of plastic, silicone, glass, acrylate and rubber. It is suitable for use in high-level disinfection of medical instruments resistant to heat.

USAGE:

- Used for endoscopic instruments by manually immersion method.
- Detro Plus PAA is diluted by 1.5% (15 ml of product per 1 L water) and filled into a clean and closed container.
- Pre-cleaned and rinsed medical devices (medical instruments) are immersed in the ready-to-use Detro Plus PAA solution so that the surface and all cavities are filled.
- The container is closed and waited for the effect time.
- After the action period, medical devices (medical instruments) are rinsed with sterile or distilled water.
- Is checked with test strips.
- It should not be used on nickel, chrome, plating and aluminum materials.
- Instruments should not be left in the solution for more than the effect time specified in the instructions for use.
- Its packaging must be kept tightly closed.

PACKAGE :

QUANTITY	PACKING TYPE	BARCODE	CATALOG CODE
5L	4 x DRUM	8680097103314	S-M.DET.1.0015

USAGE AREAS:

- Used for high level disinfection of flexible endoscopes in Detrowash series endoscope washing and disinfection devices. It does not harm plastic, silicone, glass, acrylate, rubber and rubber materials.

USAGE :

- Designed to be used with Detrowash series.
- Place the drum in the disinfectant compartment in the device.
- Place the concentrated disinfectant inlet of the device into the drum.
- The solution is automatically diluted by 0,7%.
- Perform the disinfection process in accordance with the device user manual.
- Instruments should not be left in the solution for more than the effect time specified in the instructions for use.
- Its packaging must be kept tightly closed.
- It should not be used on nickel, chrome, plating and aluminum materials.

PACKAGE :

QUANTITY	PACKING TYPE	BARCODE	CATALOG CODE
5L	4 x DRUM	8680097103321	S-M.DET.1.0014

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. Sterli 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. II2 2195-MED-1118102 Rev.13

SZUTEST

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

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

SERTİFİKA

Medikal Cihazlar Kalite Yönetim Sistemi

SERTİFİKA NO: 31732601

DETRO HEALTHCARE KİMYA SANAYİ A.Ş.

Merkez : Atatürk Mah. Cemal Gürsel Cad. No:8 ESENYURT İSTANBUL/TÜRKİYE

Şube : Atatürk Mah. Adnan Menderes Cad. No:7 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	17.11.2020
Geçerlilik Tarihi	16.11.2023
Revizyon Tarih/No	20.05.2021 / 5

TÜRKAK BDS NO
YS-EDA7-72C5

TÜRKAK
Tıbbi Cihazlar K Y S
TS EN ISO/IEC 17021
AB-0044-YS

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.

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31732601

DETRO HEALTHCARE KİMYA SANAYİ A.Ş.

Head Office : Atatürk Mah. Cemal Gürsel Cad. No:8 ESENYURT İSTANBUL/TÜRKİYE

Branch Office : Atatürk Mah. Adnan Menderes Cad. No:7 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	17.11.2020
Expiry Date	16.11.2023
Revision Date/No	20.05.2021 / 5

TÜRKAK BDS NO
YS-EDA7-72C5

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.