



EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/EEC

Company name : Detro Healthcare Kimya Sanayi A.Ş.¹

Adress 1 : Atatürk mh. Cemal Gürsel cd. No:8 Esenyurt / İSTANBUL²

Adress 2 : Atatürk mh. Adnan Menderes cd. No:7 Esenyurt / İSTANBUL³

We declare that our **Medical Device Disinfectants** that stated their models and GMDN codes in **Annex-1 Product Model and GMDN Code Chart**, that are used for disinfection of Medical devices including invasive devices and instruments;

Are produced according to Harmonized Standarts

EN ISO 13485:2016

EN ISO 14971:2019

EN 15223-1: 2016

EN 1041:2008

EN 14476:2013

EN 62366: 2008

EN 14155: 2011

EN 13624: 2003

EN 14348: 2005

EN 14347: 2005

EN 14561: 2006

EN 14562: 2006

EN 14563: 2008

EN 13727: 2012


EN 13704: 2018

¹ 05.06.2017 dated 3. revision

² 15.03.2021 dated 9. revision relating central address changing

³ 20.07.2015 dated 1. revision

⁴ 18.01.2016 dated 2. revision

 Integrated Disinfection Solutions	CE DECLARATION			
	Document no	Publish date	Revision no	Revision date
	TD. ECD.01	15.05.2013	09	15.03.2021

And conform to

Medical Device Directive 93/42/CE Annex II (Excluding matter 4)

**Full Quality Assurance System
Medical Device Disinfectant
Class IIb
(93/42/CE Annex IX, Rule 15)**

Notified Body : Szutest Uygunluk Değerlendirme A.Ş.

Notified Body ID number : 2195

Certificate No : 2195-MED-1118102

Certificate Publish Date : 30.06.2011

Certificate Expiry Date : 28.04.2024⁵

Declaration Date : 15.01.2021⁶

Declaration Place : İstanbul

Declared by / Title : Şevket Kılıç/General Manager

Confirmation : 

⁵ 28.04.2019 dated 7. revision

⁶ 05.06.2017 dated 3.revision

CE DECLARATION

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Revision date

TD. ECD.01

15.05.2013

09

15.03.2021

Product Brand/Model/Size and GMDN Codes Chart:

Brand	Model	Brand	Model	Brand	Brand	Sizes	Class	GMDN
DETROX	DETRO OPA	STERICHEM	STR DIS 1005	AKADIA-CHEMIE	-	100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	47631 – Medical Device Disinfectant
	DETRO PLUS OPA		STR DIS 1011		-	100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	47631 – Medical Device Disinfectant
	DETRO PLUS		STR DIS 1012		-	100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	40579 – Glutaraldehyde
	DETRO FORTE		STR DIS 1004		-	100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	40579 – Glutaraldehyde
	DETRCID ENDO		-		AKADENT	100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	47631 – Medical Device Disinfectant
	DETRCID ENDO READY		-		AKADENT READY	100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	47631 – Medical Device Disinfectant
					AKADENT EXTRA	100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	47631 – Medical Device Disinfectant
	DETRCID ENZYM					100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	47631 – Medical Device Disinfectant

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Product Brand/Model/Size and GMDN Codes Chart;

Brand	Model	Brand	Model	Brand	Model	Size	Class	GMDN
DETROX	DETRO ACTIV					50gr,100 gr,750 gr,1 kg,1,5 kg,2 kg,2,5 kg, 5kg, 6kg,10 kg ,20 kg	Iib	47631 – Medical Device Disinfectant
	DETROCID ACTIV					50gr,100 gr,750 gr,1 kg,1,5 kg,2 kg,2,5 kg, 5kg, 6kg,10 kg ,20 kg	Iib	47631 – Medical Device Disinfectant
	DETRO PAA 1500					500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	40580- Sterilant , Peracetic acid
	DETRO PAA 2200					500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	40580- Sterilant , Peracetic acid
	DETRO PLUS PAA					500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	40580- Sterilant , Peracetic acid
	DETRO PLUS PAA DW					5 LT, 10LT	Iib	40580- Sterilant , Peracetic acid
	DETRO HEMOPLUS					5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	47631 – Medical Device Disinfectant
	Detro HEMOPLUS PAA					5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Iib	47631 – Medical Device Disinfectant

CONFIRMED BY

PREPARED BY
QUALITY MANAGEMENT
RESPONSIBLE




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GENERAL MANAGER

