



EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/EEC

**Company name** : Detro Healthcare Kimya Sanayi A.Ş.<sup>1</sup>  
**Adress 1** : Atatürk mh. Cemal Gürsel cd. No:8 Esenyurt / İSTANBUL<sup>2</sup>  
**Adress 2** : Atatürk mh. Adnan Menderes cd. No:7 Esenyurt / İSTANBUL<sup>3</sup>

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 62366: 2008

EN 14561: 2006

EN ISO 14971:2019

EN 14155: 2011

EN 14562: 2006

EN 15223-1: 2016

EN 13624: 2003

EN 14563: 2008

EN 1041:2008

EN 14348: 2005

EN 13727: 2012

EN 14476:2013

EN 14347: 2005

EN 13704: 2018

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<sup>1</sup> 05.06.2017 dated 3. revision

<sup>2</sup> 15.03.2021 dated 9. revision relating central address changing

<sup>3</sup> 20.07.2015 dated 1. revision

<sup>4</sup> 18.01.2016 dated 2. revision

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 Deęerlendirme A.Ş.  
**Notified Body ID number** : 2195  
**Certificate No** : 2195-MED-1118102  
**Certificate Publish Date** : 30.06.2011  
**Certificate Expiry Date** : 28.04.2024<sup>5</sup>  
**Declaration Date** : 15.01.2021<sup>6</sup>  
**Declaration Place** : İstanbul  
**Declared by / Title** : Şevket Kılıç/General Manager  
**Confirmation** : 

<sup>5</sup> 28.04.2019 dated 7. revision

<sup>6</sup> 05.06.2017 dated 3.revision

## CE DECLARATION

<b>Document no</b>	<b>Publish date</b>	<b>Revision no</b>	<b>Revision date</b>
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
<b>DETROX</b>	DETRO OPA	<b>STERICHEM</b>	STR DIS 1005	<b>AKADIA-CHEMIE</b>	-	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
	DETROCID 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
	DETROCID 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
	DETROCID 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




GENERAL MANAGER

