



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 excluding 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
EN:16615:2015 <sup>4</sup>		

<sup>5</sup>

And conform to

**Medical Device Directive 93/42/CE Annex II (Excluding matter 4)**  
**Full Quality Assurance System**  
**Medical Device Disinfectant**  
**Class IIa**  
**(93/42/CE Annex IX, Rule 15)**


<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> 30.09.2020 dated 8. revision after adding standart

<sup>5</sup> 18.01.2016 dated 2. revision

**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>6</sup>  
**Declaration Date** : 15.01.2021<sup>7</sup>  
**Declaration Place** : İstanbul  
**Declared by / Title** : Şevket Kılıç/General Manager  
**Confirmation** : 

**Product Brand/Model/Size and GMDN Codes Chart;**

Brand	Model	Brand	Model	Brand	Model	Brand	Model	Size	Class	GMDN
DETROX	DETRO SEPT AF	STERICHEM	STR SP 5001	NESPERTA	SEMILAC DISINFECTION LIQUID	AKADIA-CHEMIE		100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Ila	47631 – Medical Device Disinfectant
	DETROSAN AF							100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Ila	47631 – Medical Device Disinfectant
	AKASPRAY <sup>8</sup>							100 ml, 250 ml, 500 ml, 750ml, 1 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Ila	47631 – Medical Device Disinfectant
	DETRO SAN SFC							100 ml, 250 ml, 500 ml, 750ml, 1 LT, 2 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Ila	47631 – Medical Device Disinfectant
	AKASPRAY TÜCHER						VELO ALCOHOL WIPES		150 Adet: 13,5 x 17,5 cm (PE silindir Kutu) 100 Adet: 13,5 x 17,5 cm (PE silindir Kutu) 100 Adet: 19x19 cm	Ila

<sup>6</sup> 28.04.2019 dated 7. revision

<sup>7</sup> 05.06.2017 dated 3.revision

<sup>8</sup> 05.04.2019 dated 7.revision due to new product adding

	DETRO SPRAY					250 ml, 400 ml, 500 ml, 750ml, 1 LT,2 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Ila	47631 – Medical Device Disinfectant
	DETRO SAN AF WIPES					150 X 220 mm, 180 x 200 mm, 160 x 190 mm, 175 x 260 mm, 220 x 260 mm, 135 x 175 mm, 190 x 190 mm	Ila	58077 Medical Device Cleaning / Disinfection wiping
	DETROSAN HP SPRAY					250 ml, 400 ml, 500 ml, 750ml, 1 LT,2 LT, 5 LT, 10LT, 20 LT, 200LT, 220 LT, 1000 LT	Ila	47631 – Medical Device Disinfectant
	DETROSAN HP WIPES					150 X 220 mm, 180 x 200 mm, 160 x 190 mm, 175 x 260 mm, 220 x 260 mm, 135 x 175 mm, 190 x 190 mm	Ila	58077 Medical Device Cleaning / Disinfection wiping

9

**PREPARED BY**  
QUALITY MANAGEMENT RESPONSIBLE



**CONFIRMED BY**  
GENERAL MANAGER




DETRO HEALTHCARE KIMYA SAN. A.Ş.  
Atatürk Mahallesi Adnan Menderes Caddesi  
No: 7 Esenyurt - İSTANBUL Tel : 0 212 659 77 62  
Fax: 0 212 659 77 63 - Beşikdüzü V.D.: 293 060 8762