

Document no	Publish date	Revision no	Revision date
TD. ECD.001	18.10.2019	02	02.12.2024



## EU DECLARATION OF CONFORMITY

## Medical Device Regulation(MDR)- (2017/745)

**Name of the firm:** Detro Healthcare Kimya Sanayi A.Ş.**Trade Mark:** Detrox**Authorized Person/ Title:** Şevket KILIÇ / General Manager**Address:** Atatürk Quarter, Cemal Gürsel Street, No:8/3 Esenyurt / İstanbul**Phone Number:** 0212 659 77 62**Fax Number:** 0212 659 77 63**Web / Mail:** [www.detrox.com.tr](http://www.detrox.com.tr) / [info@detrox.com.tr](mailto:info@detrox.com.tr)**SRN number:** TR-MF-000022410**Authorized Representative if any:**

For our products whose names, GMDN codes and models are defined in the table below;

Product name	Model	Size	Class	GMDN
<b>Cleaner for Surgical Instrument Washing Machines</b>	DETRO MATIC ENZYM DETRO MATIC A DETRO MATIC NS DETRO MATIC NF	5 L,	I	63385–Medical Device Cleaning Agent
<b>Brand</b>	<b>DETROX<sup>®</sup></b>			
<b>Intended purpose</b>	cleaner solutions designed for automated washing machines and manual cleaning of reusable surgical instruments. The products are used in healthcare facilities for the effective removal of organic residues, alkaline deposits, and lime scale from instruments made of metal, glass, ceramic, porcelain, and plastic. They ensure thorough cleaning and neutralization in reprocessing cycles, protecting both instruments and washing machines against corrosion. The solutions are compatible with all washer-disinfector brands and provide high cleaning performance at low usage concentrations.			
<b>Basic UDI-DI</b>	<b>868009710005061992HS</b>			

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With Relevant Harmonized standards		
EN ISO 13485: 2016	EN ISO 14971: 2019	EN 62366: 2008
EN 1041: 2008	EN 15223-1:2016	EN 13727-2012

Manufactured to harmonized standards/common specifications and

### Medical Device Regulation 2017/745/EU

**Classification: Class I (2017/745/EU Annex VIII, Rule 1)**

In accordance with its terms, We declare that this EU declaration of conformity is issued under our sole responsibility.

<b>Date of Declaration</b>	:	02.12.2024
<b>Place of Declaration</b>	:	İstanbul
<b>Declarant</b>	:	Şevket KILIÇ / General Manager
<b>Signature</b>	:	 <small>DETROX HEALTHCARE KİMYA SAN. A.Ş. Atatürk Mahallesi, Cehal Çarşısı, Çarşı No: 1, Esenyurt - İSTANBUL, Tel: 0212 659 77 62 Fax: 0 212 659 77 63 - Esenyurt M.D. 293 050 8762</small>