



EU DECLARATION

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

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Web / Mail: www.detrox.com.tr / 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
Cleaner for Surgical Instrument Washing Machines	DETRO MATIC ENZYM DETRO MATIC A DETRO MATIC NS DETRO MATIC NF	5 L,	I	63385-Medical Device Cleaning Agent
Brand	DETROX ®			
Intended purpose	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.			
Basic UDI-DI	868009710005061992HS			



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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.

Date of Declaration	:	02.12.2024
Place of Declaration	:	İstanbul
Declarant	:	Şevket KILIÇ / General Manager
Signature	:	 DETRO HEALTHCARE KİMYA SAN. TİC. AŞ. Atatürk Mah. 1. Çıkan 1. No: 10 No: 10 Esenyurt - İSTANBUL Tel: 0212 659 77 62 Fax: 0 212 659 77 63 - Esenyurt / D. 293 050 8762