

Document no	Publish date	Revision no	Revision date
TD. ECD.001	18.10.2019	03	27.07.2022

**EU DECLARATION OF CONFORMITY****Medical Device Regulation(MDR)- (2017/745)**

**Name of the firm:** Detro Healthcare Kimya Sanayi A.Ş.

**Trade Mark:** Detrox

**Individual registration number, if created:**

**Authorized Person/ Title:** Şevket KILIÇ / General Manager

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**Authorized Representative if any:**

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

Brand	Model	Size	Class	GMDN
DETROX	DETRO ENZYM	1 L, 5 L,	I	63385–Medical Device Cleaning Agent

Product name/ Trade name	Detro Enzym
Product Intended Use	Detro Enzym provides pre-cleaning of all kinds of surgical instruments, medical devices and endoscopes. It cleans organic wastes such as blood, oil, protein, starch on the surfaces. It provides a more effective cleaning by dissolving the residues on the instruments with the enzymes it contains.
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.

<b>Date of Declaration</b>	:	27.07.2022
<b>Place of Declaration</b>	:	İstanbul
<b>Declarant</b>	:	Şevket KILIÇ / General Manager
<b>Signature</b>	:	  <b>ETRO HEALTHCARE KİMYA SAN. A.Ş.</b> Atatürk Mahallesi Cemal Gürsel Caddesi No:8 Esenyurt - İSTANBUL Tel: 0 212 659 77 62 Faks: 0 212 659 77 63 - Esenyurt V.D. 293 050 8762