	EU DECLERATION			
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CE

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

Brand	Model	Size	Class	GMDN
DETROX	DETRO FORTE Test Strips	25 pcs	I	GMDN. 47056 Glutaraldehyde device disinfectant/sterilant test strip.

Product name/ Trade name	Detro Forte Test Strip
Product Intended Use	**Detro Forte is filled into a clean and closed container. Precleaned and rinsed instruments are immersed thoroughly so that all the surfaces and cavities are covered by the solution.** **The contact time is completed. Then the the instruments are rinsed with sterile or distiled water.** **The solution in the container can be used during 28 days.**

	The activity should be controlled daily by test strips, the solution should be renewed when the strips doesn't give the active colour exisiting on the strip tubes.
Basic UDI-DI	**86800971014756WK**

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

Classifation: 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	:	14.07.2022
Place of Declaration	:	İstanbul
Declarant	:	Şevket KILIÇ / General Manager
Signature	:	detrox ETRO HEALTHCARE KIMYA SAN. A.Ş. atürk Mahallesi Cemal Gürsel Caddesi :8 Esenyurt - İSTANBUL Tel: 0 212 659 77 62 ıx:0 212 659 77 63 - Esenyurt V.D. 293 050 8762