ADRANOX	EU DECLARATION OF CONFORMITY **Medical Device**

Manufacturer:	**ADRANOX Srl** Registered office: Via Imre Nagy, 46 – 46100 Mantova - Italy Headquarters: Via I° Maggio, 29 – 46051 San Giorgio Bigarello (MN)
Single registration number ('SRN' – Art. 31)	IT-MF-000027181
Medical Device:	***LYSONOX D1***
Description / Intended use:	LYSONOX D1 is a new generation multi-enzymatic detergent, with medium alkalinity, for automatic and manual reprocessing of thermostable and thermolabile medical devices. It is particularly suitable for the preliminary removal of blood, tissue residues and organic contaminants in general, from reusable medical devices.
Models:	**AD001WD**; **AD001WDL**; **AD002WD**; **AD003WD**; **AD004WD**
REF:	**AD001WD** – 5L canister; **AD001WDL** – 5L canister, oblong; **AD002WD** –10L canister; **AD003WD** –25L canister; **AD004WD** –220L canister
BASIC UDI-DI:	**805630441LYSONOX-----D19Y**
Risk Class:	**Class I not sterile** – Rule 1 Annex VIII MDR 2017/745
Conformity Assessment Procedure:	In accordance with Annex II (Technical Documentation) and Annex III (technical documentation on post-marketing surveillance)
Common Specifications Applicable:	Not applicable

We hereby, ADRANOX srl
DECLARE

under our own responsibility that the medical devices meet all the applicable provisions of the Regulation 2017/745 (MDR) on medical devices and subsequent amendments.

For this purpose, ADRANOX srl guarantees, under its own responsibility, what follows:

- the medical device described above complies with the General Safety and Performance Requirements of Annex I of MDR 2017/745 Regulation (and subsequent amendments);
- the medical device described above is manufactured according to the technical documentation provided for in Annex II of Regulation 2017/745 (MDR) and subsequent amendments; the Technical Documentation is kept at the ADRANOX srl headquarters;
- ADRANOX srl has established a systematic procedure aimed to evaluate the experience acquired in the use of medical devices in the post-production phase, in accordance with Annex III of the MDR 2017/745 Regulation and subsequent amendments. This procedure aims also to provide an appropriate system to apply to any necessary corrective measures, in the event of accidents, in accordance with the provisions of Art. 87 of the MDR 2017/745 Regulation and subsequent amendments;
- ADRANOX srl commits to keep and make the technical documentation available to the competent authorities, for a period of at least ten years from the last date of manufacture of the product.
- the medical device described above is sold in NON-STERILE packaging;
- the medical device described above IS NOT A MEASURING INSTRUMENT;
- the medical device described above has been subjected to risk assessment based on the UNI CEI EN ISO 14971 standard;
- the medical device described above IS NOT INTENDED FOR CLINICAL INVESTIGATIONS;

Date: 27/07/2023

Raffaele BACCHI
Owner and Vigilance Responsible

ADRANOX SRL
Via Imre Nagy, 46 - 46100 MANTOVA
Società a Socio Unico - P. IVA 02445730200

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