



Franklab®
notre expertise l'Ultra-Propreté

DCE 435
F4v8_08.2020_EN

DECLARATION OF CONFORMITY

The manufacturer: FRANKLAB
Z.A. De L'Observatoire
3 Avenue de Frênes
78180 Montigny-Le-Bretonneux
FRANCE

Hereby declares that, the following product:

ENZYMEX L9,
Class IIb Medical device according to rule 15 of annex IX of Medical Device
Directive 93/42/EEC

Is manufactured and delivered in accordance with the following directives:

Medical Device Directive 93/42/EEC (14 June 1993)
Public Health Code: Part 5 Book II

This statement of conformity is based on Technical File (DT Générique 1) constituted according annex II.3 of Medical Device Directive 93/42/EEC and the EC certificate delivered by the GMED (certificate n°28791 rev. 12 of 28 July 2020), notified body n°0459.

The product is placed on the market with the following packaging:

ENZYMEX L9

- 1L dosing bottle Ref.: 1043501
- 5L can Ref.: 1043505
- 25mL dose Ref.: 1043565

10th August 2020,

Julien CHARRAT
General Director

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