



**Franklab®**  
notre expertise l'Ultra-Propreté

DCE 435  
F4V9\_05.2021\_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. 13 of the 7<sup>th</sup> May 2021), notified body n°0459.

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

### ENZYMEX L9

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

7<sup>th</sup> May 2021,

Julien CHARRAT  
General Director

