



UE DECLARATION OF CONFORMITY



INOCLIC

Réf du doc : CE-710693

Validé : 22/12/23

We,

Name of manufacturer	INTELLIGENCE ARTIFICIELLE APPLICATIONS – I2A
Adress	401 avenue du Walhalla 34000 Montpellier FRANCE
Single Registration Number (SRN)	FR-MF-000021688

declare under our sole responsibility that the in vitro diagnostic medical device:

Name of product	Inoclic	References	040001 040004	INOCLIC short – Cdt : 250 INOCLIC long – Cdt : 250
Description	The Inoclic is used to produce an inoculum by allowing the transfer of a quantity of bacteria from an agar plate to a liquid medium ready to be inoculated. The Inoclic is a device designed to take a defined quantity of bacteria from the surface of a culture plate in a standardised manner. The Inoclic is then discharged into a suitable volume of physiological water to make what is called an inoculum.			
Risk class	A			
Basic UDI-DI	366662804001E7			
CND code	W0203010185 (Antibiotic susceptibility analyzers – consumables)			
GMDN code	64901 (Inoculum preparation tool IVD)			
GIVD code	24.01.10.01 (SI Hardware + accessories + consumables + software)			

complies with the essential requirements of following european directives:

Regulation 2017/746/EU	<i>Of the european parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU</i>
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The presumption of conformity is based on the application of the following standards:

EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971	Medical devices — Application of risk management to medical devices
EN ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 18113-1	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
EN ISO 18113-2	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use
EN 62366	Medical devices — Application of usability engineering to medical devices

Conformity assessment procedure	Set out in article 48.10 of regulation (EU) 2017/746 (Annex II and III)
Name and identification number of Notified body	Not applicable

Montpellier, 22/12/2023,

Name and function of signatory:
Jean-Philippe Duvergé - President