

	UE DECLARATION OF CONFORMITY	CE IVD
	SIRSCAN® DISCS DISPENSER	Réf: CE-710704 Version 04

We,

Name of manufacturer	INTELLIGENCE ARTIFICIELLE APPLICATIONS – I2A
Address	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	SIRscan® Disc dispensers	References	800226	Round dispenser of 6 discs
			800256	Square dispenser of 16 discs
Intended use of product	SIRscan® Disc dispensers are manual dispensers designed for use by laboratory professionals to place antibiotic discs on agar culture media for the purpose of performing antibiotic susceptibility testing according to standardized methods.			
Risk class	A			
Basic UDI-DI	366662880008GH			
EMDN code	W02079003 - DISPENSERS			

complies with the essential requirements of following european directives:

Regulation 2017/746/EU	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
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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 ISO 20417	Medical devices — Information to be supplied by the manufacturer
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 the conformity assessment body (if consulted)	Not applicable
Certificate reference number (if applicable)	Not applicable

Montpellier,
Validé : 04/03/26

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

