

	UE Declaration of conformity	CE IVD
	CULTURE MEDIUM MH / MHR-SIR®	Réf: CE-2674 Version 06

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	MH – MHR®	References	020001	Mueller Hinton-Round plate-90 mm
			020002	Mueller Hinton-Square plate-120 mm
			020502	MHR-SIR-Square plate-120 mm
Intended use	General agar culture medium composed of a Mueller Hinton base used in combination with antibiotic discs or CMI strips for performing antibiograms.			
Risk class	A			
Basic UDI-DI	366662802002DT			
EMDN code	W0104010403 – Susceptibility test media (plates)			

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 13612	Performance evaluation of in vitro diagnostic medical devices
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 23640	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
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 (if consulted)	Not applicable
Certificate reference (if applicable)	Not applicable

Montpellier,
Validé : 30/01/26

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

