



UE DECLARATION OF CONFORMITY



SIRSCAN ORION®

Réf du doc: CE-2440

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	SIRscan Orion®	Reference	100007
Description	The SIRscan ORION® is an automated instrument allowing: - the incubation of agar plates according to the recommendations of the guidelines (time, temperature) - a standardised reading of antibiograms in agar medium. Its incubation function allows the growth of bacterial colonies after seeding and the deposit of antibiotic discs. Its reading function allows the detection and measurement of the diameters of the inhibition zones around each antibiotic-impregnated disc.		
Risk class	A		
Basic UDI-DI	366662810004DU		
CND code	W0203010180 (Antibiotic Susceptibility Analyzers & software)		
GMDN code	56737 (Antimicrobial susceptibility analyser IVD, automated)		
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>
Directive 2006/42/EC	<i>of the European Parliament and of the Council of 17 May 2006 on machinery</i>
Directive 2009/104/EC	<i>of the European Parliament and of the Council of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work</i>
Directive 2011/65/EU	<i>of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Text with EEA relevance (RoHS3 - Consolidated Version : 09/01/2020)</i>
Directive 2013/35/EU	<i>of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)</i>
Directive 2014/30/EU	<i>of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility</i>
Directive 2014/35/EU	<i>of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits</i>





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The presumption of conformity is based on the application of the following standards:

IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
IEC 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 1037	Safety of machinery — Prevention of unexpected start-up
EN ISO 12100	Safety of machinery — General principles for design — Risk assessment and risk reduction
EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 13849-1	Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design
EN ISO 13857	Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs
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 18113-3	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use
EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
EN 61326-2-6	Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 2-6: Particular requirements. In vitro diagnostic (IVD) medical equipment
EN 62311	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)
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

