



Title: **Thermal cyler nucleic acid amplification analyser IVD, laboratory, semi-automated(IVDR)**

Document type: **Declaration of Conformity (IVDR) (v15.0)**

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EU IVDR Declaration of Conformity

Thermal cyclers nucleic acid amplification analyser IVD, laboratory, semi-automated

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name	Thermal cyclers nucleic acid amplification analyser IVD, laboratory, semi-automated
Manufacturer Name	AusDiagnostics Pty Ltd
Manufacturer Address	290-292 Coward Street, Mascot, NSW 2020 Australia
SRN	AU-MF-000020558
Basic UDI-DI	93430440W02039006V6
Variants	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose	For in vitro diagnostic (IVD) use by suitably trained personnel in qualified laboratories using corresponding AusDiagnostics panels.
IVDR Classification	Class A [Rule 5]
Notified Body	Not applicable for Class A
CE Certificate	Not applicable for Class A
EU Authorised Representative	R-Biopharm AG. An der Neuen Bergstraße 17, 64297 Darmstadt, Germany.
EU Authorised Representative SRN	DE-AR-000050025
IVDR Assessment Route	<i>For Class A: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the</i>

technical documentation in Annexes II and III of the EU IVDR 2017/746.

Appendix I – Applicable Standards

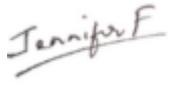
This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
IVDR 2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling, and information supplied - Part 1: General requirements.
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer.
EN ISO 18113-1:2024	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements.
BS EN 61010-1:2010+A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - General requirements
BS EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes
ISO 23783-1:2023	Automated liquid handling systems — Part 1: Vocabulary and general requirements
ISO 23783-2:2023	Automated liquid handling systems — Part 2: Measurement procedures for the determination of volumetric performance
ISO 23783-3:2023	Automated liquid handling systems — Part 3: Determination, specification and reporting of volumetric performance

Appendix II – Product Listing/Schedule

Catalogue Number	Version	UDI-DI	Description/ Name	EMDN Code
91501	01	09343044002298	HighPlex System	W02039006
94601	01	09343044004490	UltraPlex 3 System	W02039006
96501	01	09343044005831	HighPlex Ascend System	W02039006
96521	01	09343044005848	RIDA®Xplore System	W02039006
96221	01	09343044005411	RIDA®Jump System	W02039006

Appendix III - Authorised Signatory

Name	Jennifer Fernandes
Title	Regulatory Affairs and Quality Assurance (Assistant Manager)
Signature	
Date	21 November 2025
Place	Sydney, Australia

Appendix IV - Document History

Revision	Date	Change Description
9.0	21 Nov 2025	Updated EU Authorised Representative name and SRN. Updated Standards list in Appendix I - Applicable Standards table.
8.0	19 Feb 2025	Updated the wording of the Intended Purpose and added the product code 94601, 96501, 96521 and 96221.
7.0	04 Dec 2024	Updated the wording of the Intended Purpose to match with Instruction for Use. Removed the systems product codes - Ref 94601, 96501 and 96521 from the DoC.

6.0	30 Oct 2024	Added Product reference 96501 and 96521.
5.0	08 Jul 2024	Updated Basic UDI-DI to 93430440W02039006V6 from 9343044048033APE
4.0	12 Jun 2024	Added Place of signature in Appendix III - Authorised Signatory table & added Appendix IV - Document History table.
3.0	31 Oct 2023	Update device description for HighPlex & UltraPlex. Updated Standards list in Appendix I - Applicable Standards table.
2.0	12/05/2022	UDI-DI added
1.0	22/04/2022	Original version