

AusDiagnostics PTY Ltd

Title	Nucleic acid sample preparation instrument IVD, automated
Document type	Declaration of Conformity (IVDR) (15.0)
Document ID	DoC2-2
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EU IVDR Declaration of Conformity

Nucleic acid sample preparation instrument IVD, 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	Nucleic acid sample preparation instrument IVD, automated
Manufacturer Name	AusDiagnostics Pty Ltd
Manufacturer Address	290-292 Coward Street, Mascot, NSW 2020 Australia
SRN	AU-MF-000020558
Basic UDI-DI	93430440W02050106U2
Variants	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose	For automated purification of nucleic acids from appropriate human specimen types.
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	For Class A: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the 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):

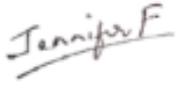
Standard/CS/Document Name	Description
IVDR 2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 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
*EU Directive 2011/65/EU	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011
*Directive 2015/863	Directive 2015/863 amends EU on the restriction of the

use of Hazardous Substances (RoHS)

Appendix II – Product Listing/Schedule

Catalogue Number	Version	UDI-DI	Description/ Name	EMDN Code
93100*	02	09343044003578	*MT-Prep 24 system	W02050106
93600	01	09343044004339	MT-Prep XL System	W02050106
96420*	01	09343044006166	*RIDA®Xtract 24	W02050106

Appendix III - Authorised Signatory

Name	Jennifer Fernandes
Title	Regulatory Affairs and Quality Assurance (Assistant Manager)
Signature	
Date	04 February 2026
Place	Sydney, Australia

Appendix IV - Document History

Revision	Date	Change Description
8.0	04 Feb 2026	Updated the standards list for applicable products (*).
7.0	09 Jan 2026	Updated EU Authorised Representative name and SRN. Updated Standards list in Appendix I - Applicable Standards table.
6.0	16 Jun 2025	Added Ref 96420 - RIDA®Xtract 24.
5.0	08 Jul 2024	Updated Basic UDI-DI to 93430440W02050106U2 from 9343044060736APA
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	Added 93600 MT-Prep XL System and Updated Standards list

		in Appendix I - Applicable Standards table.
2.0	12/05/2022	UDI-DI added
1.0	26/04/2022	Original version