Declaration of Conformity

for the Nucleic acid amplification mastermix reagent IVD

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 amplification mastermix reagent IVD
Legal Manufacturer: (Name on Label)	**AusDiagnostics Pty Ltd** 290-292 Coward Street Mascot, NSW 2020 Australia
SRN:	AU-MF-000020558
Basic UDI-DI:	9343044062623APB
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:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
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.*

Name Axel Johannsson **Position** Regulatory Affairs & Quality Assurance Manager

Signed **Date** 12-May-2022 **Place** MASCOT

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

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
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 information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements

Appendix II – Product Listing/Schedule

Catalogue Number	UDI-DI	Device Description	EMDN Code
40231	09343044003080	Low DNA Reagent Cassette	W0105900102
40241	09343044003073	Demi DNA Reagent Cassette	W0105900102
40331	09343044003103	Low RNA Reagent Cassette	W0105900102
40341	09343044003110	Demi RNA Reagent Cassette	W0105900102
40421	09343044003653	Medium DNA Reagent Reservoir (4 pack)	W0105900102
40431	09343044003660	Low DNA Reagent Reservoir (4 pack)	W0105900102
40521	09343044003684	Medium RNA Reagent Reservoir (4 pack)	W0105900102
40531	09343044003691	Low RNA Reagent Reservoir (4 pack)	W0105900102

Version History

Version	Compiled by	Date	Description
2.0	Axel Johannsson	12/05/2022	UDI-DI added and lowest level EMDN Code
1.0	Axel Johannsson	28/03/2022	Original version