AusDiagnostics

Declaration of Conformity

For Multiple respiratory virus nucleic acid IVD, reagent

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Commission Directive 2011/100/EU of 20 December 2011.

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Multiple respiratory virus nucleic acid IVD, reagent
Manufacturer:	AusDiagnostics Pty Ltd, 290-292 Coward Street, Mascot, NSW, 2020, Australia
Variants:	As per Appendix II – Product Listing/Schedule
Intended Use:	For the identification of pathogens in nucleic acid extracts from appropriate human respiratory specimen types.
Intended User:	Professional user
IVD Directive Category:	General
Notified Body:	N/A
CE Certificate Reference:	N/A
IVD Directive Assessment Route:	Conformity with the procedure referred to in Annex III, excluding 6, and drawing up the Declaration of Conformity.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Signed		**Date**	29/07/2021
Name	Axel Johannsson	**Position**	Regulatory Affairs and Quality Assurance Manager

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 his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/ Document	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling, and information supplied - Part 1: General requirements
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

Appendix II – Product Listing/Schedule

Part/ Catalogue Number	Version	Description/Name	GMDN Code
20081P	08 & 09	Step 2 Plates for SARS-CoV-2, Influenza and RSV 8-well	47923
20081S	08 & 09	Step 1 tubes for SARS-CoV-2, Influenza and RSV 8-well	47923
20602P	19	Step 2 Plates for Respiratory Viruses (16-well)	47923
20602S	19	Step 1 tubes for Respiratory Viruses (16-well)	47923
80081P	02 & 03	Step 2 Plates for SARS-CoV-2, Influenza and RSV 8-well	47923
80081S	02 & 03	Step 1 tubes for SARS-CoV-2, Influenza and RSV 8-well	47923

Version	Compiled by	Date	Description
05	Axel Johannsson	29/07/2021	2011/100/EU referenced. Date & REF 20602S corrected May 2022
04	Axel Johannsson	04/06/2021	Added v09/03 of 20081/80081 Removed v18 of 20602
03	Axel Johannsson	08/03/2021	Updated harmonised standards
02	Axel Johannsson	30/10/2020	80618 removed
01	Axel Johannsson	23/10/2020	First issue.