AusDiagnostics
Multiplexed Diagnostics | Affordable Healthcare

Declaration of Conformity

Multiple respiratory pathogen (Annex II) nucleic acid IVD, control

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 pathogen (Annex II) nucleic acid IVD, control
Manufacturer:	AusDiagnostics Pty Ltd, 290-292 Coward Street, Mascot, NSW, 2020, Australia
Variants:	As per Appendix II – Product Listing/Schedule
Intended Use:	For use as positive controls for appropriate AusDiagnostics panels.
Intended User:	Professional user
IVD Directive Category:	List B, Annex II
Notified Body:	TÜV SÜD Product Service GmbH - Notified Body: #0123
CE Certificate Reference:	V1 003496 0007 Rev. 00
IVD Directive Assessment Route:	EC Declaration of Conformity in accordance with Annex IV (full quality assurance), excluding 4 and 6.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Signed		**Date**	03/11/2021
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
91011	08	Synthetic Positive Controls for Respiratory Pathogens	61317
91071	02	Synthetic Positive Controls for Atypical Pneumonia	61317

Version	Compiled by	Date	Description
05	Axel Johannsson	03/11/2021	New IVDD certificate, Signature date corrected
04	Axel Johannsson	29/07/2021	2011/100/EU referenced
03	Axel Johannsson	08/03/2021	Updated harmonised standards
02	Axel Johannsson	24/02/2021	Updated EC Certificate
01	Axel Johannsson	27/10/2020	First issue.