AusDiagnostics
Multiplexed Diagnostics | Affordable Healthcare

EC Declaration of Conformity

Manufacturer:	AusDiagnostics Pty Ltd 290-292 Coward Street Mascot NSW 2020 Australia
European Representative:	AusDiagnostics UK Ltd Unit 3, Anglo Business Park, Asheridge Road Chesham, Buckinghamshire, HP5 2QA United Kingdom
Product:	Respiratory Viruses (16-well) REF 20602 VER 16 Consisting of the separately sold component IVDs: Step 1 Tubes for Respiratory Viruses (16-well) REF 20602S VER 16 Step 2 Plates for Respiratory Viruses (16-well) REF 20602P VER 16
Classification:	Not List A or B according to Annex II and not for Self-Testing
Conformity Assessment Route:	Annex III (excluding 6)

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC for medical devices. All supporting documentation is retained by the manufacturer.

Standards Applied:

EN ISO 13485:2016 (TÜV SÜD Certificate #Q1N 18 02 03496 001)

Medical devices - Quality management systems - Requirements for regulatory purposes

EN 13612:2002

Performance evaluation of in vitro diagnostic medical devices

EN ISO 14971:2012

Medical devices - Application of risk management to medical devices

EN ISO 15223-1:2016

Medical devices - Symbols to be used with medical device labels, labelling, and information supplied - Part 1: General requirements

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 23640:2015

In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

EN 62336:2008

Medical Devices - Application of usability engineering to medical devices

Notified Body: N/A

(EC) Certificate(s): N/A

Start of CE-marking: 23/06/2018

Place, Date of Issue: Sydney, Australia 03/07/2019

Signature:

Axel Johannsson

Regulatory Affairs and Quality Assurance Manager

Keith Stanley

Managing Director