EC Declaration of Conformity

According to Regulation Annex No. 3 of the IVD Directive *98/79/EC* of the European Parliament and of the Council dated October 27,1998, on *in vitro* diagnostic medical devices and Commission Decision 2010/227/EU.

This is to certify that following IVD product:

ZENA MAX Measles (MeV) Real Time PCR Detection Kit

Classified as:

"All other IVD Medical Devices" according to Annex I rules

Manufactured by:

AMD Ltd.
BIOCITY Nottingham, Pennyfoot Street, Nottinghamshire, NG1 GF

Quality Management System:

Certified According to ISO 13485:2016

Complies with all essential requirements of Annex No.1 of the Directive *98/79/EC* of the European Parliament and the Council and the Commission Decision 2010/227/EU and under normal use it is safe for its intended purpose. The manufacturer has taken measures assuring compliance of all medical agents introduced into the market with the technical documentation with the basic requirements.

Procedure described in Annex No. 3 of the Directive *98/79/EC* of the European Parliament and of the Council and the Commission Decision 2010/227/EU was used to evaluate the basic characteristics of the product by the designated method.

Authorised Representative: AMD Ltd

BIOCITY Nottingham, Pennyfoot Street, Nottingham,

Nottinghamshire, NG1 1GF, United Kingdom

Tel: +44 115 969 9934

..... Date: 21/08/2019

Quality Control Dept.
AMD Ltd.

Addendum for Declaration of Conformity

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009 and Commission Directive 2011/100/EU.

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 of the DOC	**ZENA MAX Measles (MeV) Real Time PCR Detection Kit**
Manufacturer	AMD Ltd, BioCity Nottingham, Pennyfoot Street, Nottingham, NG1 1GF United Kingdom
Variants	N/A
Intended Use	Real Time PCR Detection kit for the detection of Measles (MeV) in human samples.
Intended User	Professional Use Only
Notified Body	N/A
CE Certificate Reference	N/A
IVD Directive Assessment Route	General IVD
EU Authorised Representative	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR, 4013 Malta

..... Date: 14.06.24

Quality Control Dept.
AMD Ltd.

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 Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
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 13485:2015+A11:2011	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012/ISO 14971:2019	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.

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
KD919189-100	ZENA MAX Measles (MeV) Real Time PCR Detection Kit	49276

Version History

Version	Compiled by	Date	Description
1-0	Kate Watson / Irene Bnochi	21.08.2019	First issue
1-1	Hannah Betts	14.06.2024	Non-significant updates

This Declaration of Conformity issued on August 21st 2019 is kept unchanged, the update consists only of non-significant changes.