Declaration of Conformity

for VISITECT® CD4 Advanced Disease Rapid Test

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:	VISITECT® CD4 Advanced Disease Rapid Test
Manufacturer:	AccuBio Ltd, Units 1-12, Hillfoots Business Village, Alva, Clackmannanshire, FK12 5DQ, Scotland, United Kingdom
Variants:	• AB376 – 25 Tests • AB376N – 25 Tests • AB376BR – 25 Tests
Intended Use:	Rapid test for the estimation of CD4+ T cells in human whole blood.
Intended User:	For Professional Use Only
IVD Directive Category:	General IVD
Notified Body:	N/A
CE Certificate Reference:	N/A
IVD Directive Assessment Route:	Annex III
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Laura Allan **Position** Quality Assurance & Regulatory Affairs Manager

Signed Laura Allan **Date** 30 May 2023

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.

Digitally signed by Bolea Petru
Date: 2023.10.23 13:13:04 EEST
Reason: MoldSign Signature
Location: Moldova

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 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN 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
EN ISO 23640:2015	Evaluation of stability of in vitro diagnostic reagents
EN ISO 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 13612:2002	Performance Evaluation of in vitro diagnostic medical devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
AB376	CD4 cell marker IVD, kit, immunochromatographic test (ICT), rapid	63165
AB376N	CD4 cell marker IVD, kit, immunochromatographic test (ICT), rapid	63165
AB376BR	CD4 cell marker IVD, kit, immunochromatographic test (ICT), rapid	63165

Version History

Version	Compiled by	Date	Description
1.0	Eilidh MacKenzie	30 May 2023	First issue with AccuBio Ltd as the legal manufacturer. Device previously CE Marked and placed on the EU market by Omega Diagnostics.