

DECLARATION OF CONFORMITY

Name of Manufacturer Aidian Oy
Single Registration Number of the Manufacturer (SRN) FI-MF-000023611
Address Koivu-Mankkaan tie 6 B, FI-02200 Espoo, Finland

Product trade name	Cat. No.	Basic UDI-DI	Intended purpose	Risk Class
QuikRead go Plus Instrument	155378	6438115QRgoPlusDR	See appendix 1.	A
	155376			
	155375			
	155377			

Declaration


We hereby declare that the above-mentioned products comply with the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and the conformity assessment procedure has been performed according to Article 48, the Machinery Directive 2006/42/EC and the conformity assessment procedure has been performed according to Article 12, the RoHS III Directive 2011/65/EU and the conformity assessment procedure has been performed according to Article 4, the Electromagnetic Compatibility Directive 2014/30/EU and the conformity assessment procedure has been performed according to Annex I, and the Radio Equipment Directive 2014/53/EU and the conformity assessment procedure has been performed according to Article 3. This declaration is issued under the sole responsibility of the manufacturer.

Notified Body NA
Certificate NA
Place and Date of Issue Espoo, 9.10.2024

Aidian Oy


Juhana Rauramo
CEO




p.p. Mervi Ylianttila
Vice President, QARA Compliance and Sustainability

Appendix 1. Intended Purpose of QuikRead go Plus Instrument

QuikRead go Plus Instrument is an automated instrument designed and calibrated for both photometric and turbidimetric measurements. The instrument is intended for quantitative and qualitative determination of various QuikRead go Plus reagent kit analytes from human samples such as whole blood, serum, plasma, throat swabs and faecal samples to be used as an aid in diagnosis and treatment monitoring. QuikRead go Plus Instrument is intended to be used by healthcare professionals in clinical laboratory and near patient testing settings.