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.	UDI-DI	Intended purpose	Risk Class
QuikRead go® Instrument	133893 135867 149915	6438115QRgoInstrumentF8	See appendix 1.	A

Declaration

We hereby declare that the above-mentioned products comply with the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and with the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment including amendment Directive 2015/863/EU. The conformity assessment procedure has been performed according to Article 48. This declaration is issued under the sole responsibility of the manufacturer.

Notified Body NA

Certificate NA

Place and Date of Issue Espoo 25.05.2022

Aidian Oy

Juho Himberg
CEO

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p.p. Mervi Ylianttila
Vice President, Quality Management

Appendix 1. Intended Purpose of QuikRead go Instrument

QuikRead go 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® 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. The QuikRead go Instrument is intended to be used in clinical laboratory and near patient testing settings.