

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® Sample Collector 1µl	154457	6438115QRgoSAMPColl1uITF	See appendix 1.	A
QuikRead go® Sample Collector 10µl	153211	6438115QRgoSAMPColl10uIQK	See appendix 1.	A
QuikRead® Plungers	67966	6438115QRPlungersA7	See appendix 1.	A
QuikRead® Capillaries	67962	6438115QRCapillaries9N	See appendix 1.	A
QuikRead go® Capillaries	147851	6438115QRgoCapillariesU8	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. 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

06.06.2022

Aidian Oy



Juho Himberg
CEO



p.p. Mervi Ylianttila
Vice President, Quality Management

Appendix 1.**Intended Purpose of QuikRead go Sample Collector 1µl**

QuikRead go Sample Collector 1 µl is intended to collect and transfer finger prick capillary blood or anticoagulated (EDTA or heparin) venous whole blood to enable QuikRead go® HbA1c to be used as intended.

Intended Purpose of QuikRead go Sample Collector 10µl

QuikRead go Sample Collector 10µl is intended to collect and transfer finger prick capillary blood or anticoagulated (EDTA or heparin) venous whole blood, or plasma, or serum to enable QuikRead go® easy CRP to be used as intended.

Intended Purpose of QuikRead Plungers

QuikRead Plungers are intended to dispense finger prick capillary blood or anticoagulated (EDTA or heparin) venous whole blood, or plasma, or serum from QuikRead® Capillaries and QuikRead go® Capillaries (to enable QuikRead® CRP, QuikRead® CRP with prefilled cuvettes, QuikRead go® CRP, QuikRead go® CRP+Hb, QuikRead go® wrCRP and QuikRead go® wrCRP+Hb to be used as intended). In addition, QuikRead Plungers are intended to dispense urine from QuikRead Capillaries (to enable QuikRead® U-ALB to be used as intended).

Intended Purpose of QuikRead Capillaries

QuikRead Capillaries with 20 µl volume are intended to collect and transfer finger prick capillary blood or anticoagulated (EDTA or heparin) venous whole blood, and plasma, or serum to enable QuikRead® CRP, QuikRead® CRP with prefilled cuvettes, QuikRead go® CRP and QuikRead go® CRP+Hb to be used as intended. In addition, QuikRead Capillaries with 20 µl volume are intended to collect and transfer urine to enable QuikRead® U-ALB to be used as intended.

Intended Purpose of QuikRead go Capillaries

QuikRead go Capillaries with 10 µl volume are intended to collect and transfer finger prick capillary blood or anticoagulated (EDTA or heparin) venous whole blood, or plasma, or serum to enable QuikRead go® wrCRP and QuikRead go® wrCRP+Hb to be used as intended.