

**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.