AIDIAN

v. 1.0

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® 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 17.5.2022

Aidian Oy

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Juho Himberg
CEO

p.p. Mervi Ylianttila
Vice President, Quality Management

Appendix 1.

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.