

Ängelholm, January 21st, 2020

HEMOCUE AB

EC DECLARATION OF CONFORMITY

Manufacturer's name: HemoCue AB

Manufacturer's address: Kuvettgatan 1
SE 262 71 Ängelholm
Sweden

Product name: HemoCue[®] Glucose 201+ Analyzer
HemoCue[®] Glucose 201 Microcuvettes

Classification: Other IVD (EU IVD Directive 98/79/EC)

Conformity Assessment route: Annex III of EU IVD Directive 98/79/EC

We, HemoCue AB, solely under our responsibility, herewith declare that the above mentioned products meet the Essential Requirements of Annex 1 and applicable provisions of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

HEMOCUE AB



Maria Fagerberg
Senior Director RA/QA