

Ängelholm, January 21<sup>st</sup>, 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® Hb 201+ Analyzer  
HemoCue® Hb 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