

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 RT Analyzer

HemoCue® Glucose 201 RT 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