Ängelholm April 24, 2023

HEMOCUE AB

EU DECLARATION OF CONFORMITY

Manufacturer's name:	**HemoCue AB** Kuvettgatan 1 SE-262 71 Ängelholm Sweden
Single Registration Number (SRN):	SE-MF-000000697
Product Name/Trade Name:	HemoCue® Glucose 201 RT Microcuvettes EMDN code: W01010213 GLUCOSE **Intended Purpose** The HemoCue Glucose 201 RT Systems are intended for quantitative determination of glucose in whole blood (capillary, venous or arterial), supplementing the clinical evidence in the diagnosis of diabetes, the detection of idiopathic hypoglycemia, monitoring patients with diabetes and monitoring neonatal blood glucose levels. The systems should not be used on critically ill neonates in neonatal intensive care settings. The HemoCue Glucose 201 RT Systems are automated systems for professional use by healthcare professionals and laboratory personnel, intended for near-patient (point-of-care) and laboratory testing. The HemoCue Glucose 201 RT Systems are for In Vitro Diagnostics use only. The HemoCue Glucose 201 RT Microcuvettes are only to be used with HemoCue Glucose 201 RT Analyzer or HemoCue Glucose 201 DM RT Analyzer.
Basic UDI-DI:	7311091147XXCK
Risk class:	The device is classified as Class C according to rule 3j and 4b of the Regulation (EU) 2017/746, Annex VIII

Notified Body name and identification number:	BSI Group The Netherlands B.V. Notified Body Number 2797
Conformity Assessment route:	Regulation (EU) 2017/746, Annex IX
Certificate number and expiry date:	IVDR 727884. Expiry date: 2027-11-03
Common specifications:	No applicable common specifications available

We, HemoCue AB, solely under our responsibility, herewith declare that the above mentioned product is in conformity with the Regulation (EU) 2017/746.

All supporting documentation is retained under the premises of the manufacturer.

HEMOCUE AB

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HemoCue – a Danaher company

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