

Device Schedule:**Intended purpose as per the Instructions for Use:**

The HemoCue® Hb 301 Analyzer is intended for quantitative near-patient (point-of-care) whole blood hemoglobin determination in primary care or blood donation settings using specially designed microcuvettes. The HemoCue® Hb 301 Analyzer is for In Vitro Diagnostic use only.

The HemoCue® Hb 301 Analyzer is an automated instrument for professional use by laboratory personnel and healthcare professionals. Indications for use is quantitative determination of hemoglobin to support clinical decisions in the detection of anemias, erythrocytosis and polycythemias.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
Hemocue Hb 301 Analyzer	1218	IVR 0605	Class B near-patient test	7311091218XXCE