

EN • RFM-202 – DEVICE

In vitro diagnostic medical device – CE marked – In compliance with the requirements of Regulation (EU) 2017/746

Cod. RFM-202

Manufacturer

Hangzhou Lysun Biotechnology Co., Ltd.

Distributor

Callegari S.r.l.

Intended Use

The Renal Function Analysis Meter is intended for the quantitative determination of creatinine (CR) in whole capillary blood, venous whole blood, plasma and serum. RMF-202 is an in vitro diagnostic medical device intended for professional use and is used only in combination with Creatinine Test Strip CRS-102.

Technical Features

MEASURING PRINCIPLE	Reflectance photometer
ANALYSIS TIME	Approximately 5 minutes
MEASUREMENT RANGE	0.044 mmol/L - 1.320 mmol/L 0.50 mg/dL - 14.93 mg/dL
SPECIMEN	Capillary and venous whole blood, plasma, serum
SPECIMEN VOLUME	35 µL
POWER SOURCE	3 1.5 V AAA batteries
UNITS OF MEASUREMENT	mmol/L or mg/dL
MEMORY	500 tests
AUTOMATIC SHUT-OFF	After 5 minutes of inactivity
DIMENSIONS	135 (w) × 66 (d) × 19 (h) mm
WEIGHT	90 g
TRANSPORT AND STORAGE CONDITIONS	0 °C – 55 °C; ≤ 90% RH
SYSTEM OPERATING CONDITIONS	10 °C – 35 °C; ≤ 80% relative humidity
TEST STRIP AND OPTICAL VERIFY STRIP STORAGE AND TRANSPORTATION CONDITIONS	2 °C – 30 °C; ≤ 90% RH
CONFORMITY	CE Mark