



QVC CERT
STANDARDIZING THE WORLD

2-B, Civil Lines, Yukti Business Centre, Near Old Session Court,
Ambala City - 134003, Haryana, India

CERTIFICATE

No. QVC/CE/IVD/2023-24/212

Confirmed that the product In Vitro Diagnostic Medical Devices - according to the EU Regulation IVDR 2017/746:

HaemurEx - Clinical Chemistry Analyser

(Class A - Low Risk)

Manufactured by company:

AROYAM MEDISOFT SOLUTION PVT. LTD.

ROOM NO-21, UNIT- 806, WORK NESTS, 8TH FLOOR, TOWER- 2, GODREJ WATERSIDE, DP-5, SEC-V, SALT LAKE, KOLKATA -700091, WEST BENGAL

Complies with the applicable essential requirements of the EU Regulation IVDR 2017/746 on In Vitro Diagnostic Medical Devices.

Referring to the intended use, QVC has conducted with successful results the type-examination of the certified product according to the relevant parts of the above-mentioned directive and appropriate harmonized European standards.

Based on an audit of the quality management system implemented by the manufacturer, the QVC confirms a manufacturer's ability to keep permanently the requested safety and quality level.

The manufacturer is obligated to assure that all in vitro diagnostic medical devices of the respective models conform to the type approved by this certificate. The certificate remains valid until the manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer or his representative in accordance with applicable Regulations and Standards, after fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above-referenced models, the CE-marking according to this example:



Issue Date: **06/04/2023**

Expiry Date: **05/04/2026**

Authorized Signatory

