DECLARATION LETTER

We, the manufacturer, declare under our sole responsibility that

The medical device(s) Hemonart CompactOne 9 ACT analyzer

BlacT ACT test tube, Ref: ACT3017

According to the European Directive 98/79/EC (IVD);

The classification is based on the following criteria: Annex VIII

It is classified as ***Class Others.***

Other IVD Products:

Products that are neither listed in Annex II nor intended for self-testing do not require involvement of a Notified Body in the conformity assessment procedure.

According to (EU) In Vitro Diagnostic Medical Device New Regulation No. 2017/746 (IVDR);

Tests used in emergencies to monitor critical parameters; (EU) In Vitro Diagnostic Medical Device Regulation No. 2017/746 VIII. Classification rules, according to Rule 3;

It is classified as ***Class C.***

Class C IVD Products:

They require involvement of a Notified Body in the conformity assessment procedure.

P.S. Self-declared IVD devices may be placed on the market until **26 May 2026** for Class C.

We are working on the IVDR and we will be ready before the set 26 May 2026.

Sıla Nur ÖZ

Quality Specialist