Erba Lachema s.r.o

DECLARATION OF CONFIRMITY and CALIBRATION

CE

The undersigned Erba Diagnostics Ltd., Unit 4, Block K, Vantage Suites, Central Park, Leopardstown, Dublin 18, manufacturer of diagnostic devices, with Company Quality Management System in compliance with standard ISO 13485,

declares, that the device:

Name:H560	K11042137003

complies with all the essential requirements listed in Annex I of Directive 98/79/EC and obligations specified in Annex III, art. 2 – 5 of Directive 98/79/EC for In vitro Medical-Diagnostic Devices.

Therefore Erba Lachema s.r.o. declares and assures the following:

1. The a.m. device complies with the applicable provisions of Directive 98/79/EC.
2. The a.m. device is not included in the list A and B of the Annex II of Directive 98/79/EC.
3. The manufacturer declares to have established a procedure and to maintain it in order to assure the post-marketing surveillance, according to the Directive of 98/79/EC.
4. All mentioned products are Factory calibrated and Final QC passed at the time of release.

Date of issue: Oct-2022

Manish Airan
Representative of Quality Management

Erba Diagnostics Ltd.
Unit 4, Block K, Vantage Suites, Central Park, Leopardstown, Dublin 18
www.erbamannheim.com VAT Reg No : IE3517014VH

This is an electronically generated document requires no signatures.

Certificate of Conformity and Calibration