

DECLARATION OF CONFORMITY



The undersigned Erba Lachema s.r.o., having its seat in Brno, Karásek 2219/1d, Czech Republic, manufacturer of diagnostic devices, with Company Quality Management System in compliance with standard ISO 13485,

declares, that the devices of Hematology product range listed in the annex to this declaration, comply 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 devices listed in the annex to this declaration comply with the applicable provisions of Directive 98/79/EC.
2. the devices listed in the annex to this declaration 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.

Date of issue: 26.07.2019




Milena Rikanová
Representative of Quality Management

Annex to the Declaration:

Cat. number	Product name
INS00066	ELite 3 (opened system)
INS00067	ELite 3 (closed system)
INS00068	ELite 5
HEM00001	Erba Cleaner
HEM00002	Erba Diff-5P
HEM00003	Erba Dil-5P
HEM00004	Erba Diluent-Diff
HEM00005	Erba Hypoclean CC
HEM00006	Erba Lyse-5P
HEM00007	Erba Lyse-Diff (opened system)
HEM00008	Erba Lyse-Diff (closed system)
HEM00009	ELite 5 HEM Control Low
HEM00010	ELite 5 HEM Control Normal
HEM00011	ELite 5 HEM Control High
HEM00012	ELite HEM Calibrator
HEM00013	ELite 3 HEM Control Low
HEM00014	ELite 3 HEM Control Normal
HEM00015	ELite 3 HEM Control High
HEM00016	Erba Hypoclean
HEM00017	Erba Clenz
INS00071	ELite 580
INS0007	H580
HEM00019	ELite H580 Dil
HEM00020	ELite H580 Lyse1
HEM00021	ELite H580 Lyse2
HEM00022	ELite H580 Lyse3
HEM00023	ELite H Clean
HEM00024	ELite H5 CON L
HEM00025	ELite H5 CON N
HEM00026	ELite H5 CON H
HEM00027	ELite H CAL
INS00077	H360
HEM00028	Erba H360 Dil
HEM00029	Erba H360 Lyse
HEM00033	Erba H3 CON L
HEM00034	Erba H3 CON N
HEM00035	Erba H3 CON H
INS00078	H560
HEM00030	Erba H560 Dil
HEM00031	Erba H560 Lyse 1
HEM00032	Erba H560 Lyse 2