



## DECLARATION OF CONFORMITY



The undersigned Erba Lachema s.r.o., having its seat in Brno, Karásek 1d, Czech Republic, manufacturer of diagnostic devices, with Company Quality Management System in compliance with standards ISO 9001 and ISO 13485,

declares, that the system:

Name: ELite 3

System components:

|                    |                                      |
|--------------------|--------------------------------------|
| Cat. No.: 50004170 | Name: ELite 3                        |
| Cat. No.: 50003763 | Name: Erba Diluent-Diff              |
| Cat. No.: 50004171 | Name: Erba Lyse-Diff                 |
| Cat. No.: 50003767 | Name: Erba Cleaner                   |
| Cat. No.: 50003832 | Name: Erba Hematology Control Low    |
| Cat. No.: 50003833 | Name: Erba Hematology Control Normal |
| Cat. No.: 50003834 | Name: Erba Hematology Control High   |

Product group: Hematology

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 comply 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.

Date of issue: 17.05.2011

Milena Ríkanová  
Representative of Quality Management

Erba Lachema s.r.o.  
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declares, that the system:

Name: ELite 5

System components:

|                    |                               |
|--------------------|-------------------------------|
| Cat. No.: 50003760 | Name: ELite 5                 |
| Cat. No.: 50003761 | Name: Autosampler for ELite 5 |
| Cat. No.: 50003774 | Name: Erba Dil-5P             |
| Cat. No.: 50003765 | Name: Erba Lyse-5P            |
| Cat. No.: 50003766 | Name: Erba Diff-5P            |
| Cat. No.: 50003773 | Name: Erba Hypoclean CC       |

Product group: Hematology

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.

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