PLIVA – Lachema Diagnostika s.r.o.

DECLARATION OF CONFORMITY

The undersigned PLIVA-Lachema Diagnostika s.r.o., having its seat in Brno, Karásek 1, 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: LAURA® SMART – PHAN® LAURA® diagnostic strips

System components:

Cat. No.: 50003508	**LAURA® SMART**
Cat. No.: 10010238	**DiaPHAN® LAURA®**
Cat. No.: 10008297	**DekaPHAN® LAURA®**
Cat. No.: 10010239	**PentaPHAN® LAURA®**
Cat. No.: 10008298	**HeptaPHAN® LAURA®**

comply with all the essential requirements listed in Annex I of Directive 98/79/EC (including art. 6) and obligations specified in Annex III, art. 2 – 5 of Directive 98/79/EC for In vitro Medical-Diagnostic Devices.

Therefore PLIVA-Lachema Diagnostika s.r.o. declares and assures the following:

1. The a.m. system comply with the applicable provisions of Directive 98/79/EC and its suitability for given purpose of application was clinically verified.
2. PHAN® LAURA® diagnostic strips comply with the applicable provisions of Directive 98/79/EC and are 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.

This declaration of conformity is valid for maximum 5 years.

RNDr. Milena Rikanová
Representative of Quality Management

Date: 17.05.2007

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