



## PLIVA – Lachema Diagnostika s.r.o.

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### 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® reader – PHAN® LAURA® diagnostic strips**

**System components:**

<b>Cat. No.: 50001727</b>	<b>LAURA® reader</b>
<b>Cat. No.: 10008297</b>	<b>DekaPHAN® LAURA®</b>
<b>Cat. No.: 10008298</b>	<b>HeptaPHAN® LAURA®</b>

**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: 7.11.2006

