



DECLARATION OF CONFORMITY

Immunotech a.s. hereby ensures and declares that the product(s) listed below comply with the requirements of the European Union In Vitro Diagnostic Medical Device Directive 98/79/EC.

Immunotech a.s. assure et déclare par la présente que le(s) produit(s) listé (s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Immunotech a.s. dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Immunotech a.s. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Immunotech a.s. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) / Produkt(e) / Prodotto(i) / Produit(s) / Producto(s):

FSH IRMA, Part Number IM2125 (100 tests)

FSH IRMA, Part Number IM3301 (400 tests)

Petr Šmídl
Quality Assurance and
Regulatory Affairs Manager

Date: September 15, 2004

Conformity Assessment Procedure
Annex III



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