

EC DECLARATION OF CONFORMITY

We,

Thermo Fisher Scientific Oy, Clinical Diagnostics Finland

hereby declare that the reagent kit with

Trade name:	BILIRUBIN DIRECT
Code:	981892

comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

This Declaration is valid for all batches which are placed on the market by ourselves on or after October 13, 2010 and which bear the CE marking.

Vantaa, November 01, 2010

Thermo Fisher Scientific Oy



Silja Halme
Quality Manager
Quality, Regulatory and Compliance
Clinical Diagnostics Finland