EC DECLARATION OF CONFORMITY

We,

Thermo Fisher Scientific Oy, Clinical Diagnostics Finland

declare that all Thermo Fisher Scientific Oy products listed in Appendix 1 are manufactured in compliance with ISO 9001:2008 and ISO 13485:2003 standards and are CE marked based on In Vitro Diagnostic Medical Devices Directive 98/79/EC. Product-specific declarations may be obtained from the manufacturer.

This Declaration is valid for all instrument and reagent batches which are placed on the market by ourselves on or after November 7, 2003 and which bear the CE marking.

Classification: IVD

Vantaa, December 18th, 2013

Thermo Fisher Scientific Oy

Hanna Valo
Quality Chemist
Quality, Regulatory and Compliance
Clinical Diagnostics Finland

Appendix 1

CE-marked instruments	
Code	**Product**
98630000	INDIKO
98631000	INDIKO ISE
98640000	INDIKO PLUS
98641000	INDIKO PLUS ISE

CE-marked cuvettes	
Code	**Product**
984000	Multicell cuvettes
986000	Tencell cuvettes

CE-marked ISE electrodes, calibrators, controls and other solutions	
Code	**Product**
980845	Reference electrode kit
981193	Potassium (K) Electrode
981194	Sodium (Na) Electrode
981593	Potassium Micro Volume Electrode
981594	Sodium Micro Volume Electrode
981595	Calcium Micro Volume Electrode
981596	Chloride Micro Volume Electrode
981597	pH Micro Volume Electrode
981598	Lithium Micro Volume Electrode
981998	ISE Reference for Indiko
980303	Urine Diluent
980314	Reference Electrode Solution
981714	Bag for ISE Reference
981058	Select Ion Normal
981059	Select Ion Low
981094	Select Ion High
984031	ISE Calibrator 1
984034	ISE Calibrator 4
984035	ISE Calibrator 2 & 3