ThermoFisher
SCIENTIFIC

EC DECLARATION OF CONFORMITY

Manufacturer's Name:	Thermo Fisher Scientific Oy
Manufacturer's Address:	Ratastie 2 FI-01620 Vantaa FINLAND

declares that

Product Product name	**Clinical Chemistry Analyzer** **Indiko**
Type	**863**
Product Codes:	**98630000** **98631000**

are in conformity with the provisions of the following EC directives, including the latest amendments, and with national legislation implementing these directives:

98/79/EC	IVD Directive (In vitro diagnostic medical device)
2011/65/EU	RoHS Directive (Restriction of the use of certain hazardous substances in electrical and electronic equipment)

and that the following harmonized standards have been applied:

EN ISO 13485:2003 and EN ISO 13485:2012
EN ISO 14971:2012
EN 61010-1:2001; EN 61010-2-010:2003; EN 61010-2-081:2002+A1:2003
EN 61010-2-101:2002
EN 61326-1:2006, class B; EN 61326-2-6:2006
EN 62304:2006
EN 50581:2012

In addition we comply with the Essential Health and Safety Requirements on Machinery Directive (2006/42/EC).

This Declaration for IVD Directive is valid for all devices which are placed on the market by ourselves on or after December 31st, 2010, and for RoHS Directive after July 5th, 2016, and which bear the CE marking.

Vantaa, December 8th, 2016

Thermo Fisher Scientific Oy

Sini Sipponen
Quality Manager
Quality Assurance and Regulatory Affairs
Analyzers & Automation
Clinical Diagnostics