YHLO BIOTECH

Date: 21.10.2013

Declaration of Conformity

CE

We

SHENZHEN YHLO BIOTECH CO., LTD

No. 5 Building, Lishan Industrial Area, Xinghai Road,Nanshan District,
Shenzhen Guangdong 518054, P. R .China

certifies

that the design, type of manufacture of the in vitro medical-diagnostics device described hereafter and the version distributed on the market,

conforms to the

"98/79/EEC directive relevant to the in Vitro Medical-Diagnostics Devices (IVD)"
through the accomplishment to the Annex III (except section 6) and the essential requirements of Annex I.
The certificate will lose its validity in the event of:
-modifications made to the machine in question without our authorization
-incorrect use of the instrument
-technical interventions performed by unauthorized personal
-installation of non-original spare parts

Product:	UNION Immune Analyzer
Type:	UNION-C
Technical data:	110/220 Vac (50-60Hz)

confirms

as a whole and in its parts, with the following standards and their amendments:

EN 61010-1(CE 66-5)	"Safety requirements for electrical equipment for measurement, control and laboratory use-Part1: General requirements." The instrument is classified in Class I
EN 61010-2-101	"Safety requirements for electrical equipment for measurement, control and laboratory use-Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN61326-1	"Electrical for measurement, control and laboratory use-Electromagnetic compatibility requirements –Part 1: General requirements
EN 61326-26	"Electrical Equipment for measurement, control and laboratory use-Electromagnetic compatibility requirements –Part 2-6: in vitro diagnostic (IVD) medical equipment"

And therefore meets the minimum requirements of the following Community directives and their amendments:
Low Voltage Directive (2006/95/EEC)
Electromagnetic Compatibility Directive (2004/108/EEC)

SHENZHEN YHLO BIOTECH CO., LTD

Mr.Yongbo Song
General Manager