

Declaration of Conformity

Manufacturer: WIENER Laboratorios S.A.I.C
Riobamba 2944
S2003GSD Rosario
Argentina

European Representative: MT Promedt Consulting GmbH
Altenhofstrasse 80
D-66386 St. Ingbert
Germany

Product: WL 19 Con AA nivel 2

EDMA Code: 13 01 20 01 00

Classification: "Other IVD" Non List A/Non List B/Not
for self-testing

Conformity assessment route: Annex III Applied

We herewith declare that the above-mentioned product meets the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic Devices.

Standards Applied: See next page

(EC) Certificate(s): Not applicable for this kind of product

Start of CE Marking: -

Place, date of issue: Rosario, November 1, 2010

Signature:



Viviana E. Cétola
Technical Director
Wiener Laboratorios S.A.I.C.

Standards fulfilled

Document Number	Title
EN ISO 9001:2008	Quality Management Systems
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN 13612	Performance evaluation of <i>in vitro</i> diagnostic medical devices
EN 12286	Measurement of quantities in samples of biological origin – Presentation of reference measurement procedures
EN 12287	Measurement of quantities in samples of biological origin – Description of reference materials
EN 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 13640	Stability testing of <i>in vitro</i> Diagnostic reagents
EN 375	Information supplied by the manufacturer with <i>in vitro</i> diagnostic reagents for professional use
EN 980	Terminology and symbols for use in Medical Device Labels
EN 15223	Symbols to be used with medical device labels, labeling and information to be supplied