



EC Declaration of Conformity

In accordance with Directive 98/79/EC

Manufacturer: Paramedical srl

Address: Via Antonio Amato 24/26, 84131 Salerno-ITALY

The EC Declaration of Conformity is valid for the following products:

SEE ATTACHMENT

Classification:

Clinical Chemistry Instruments

EDMA Code:

21.01.10.01

Conformity assessment route:

This declaration of conformity is based on the European in Vitro Diagnostics Medical Device Directive 98/79/EC, Annex III.

The product are not included under European in vitro diagnostic medical devices Directive 98/79/EC, Annex II. Paramedical srl is a company ISO 9001:2015 and ISO 13485:2016 certified.

We herewith declare with sole responsibility that our responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Products:	Model:
Semi Automatic Chemistry Analyzer	PKL PPC110
Semi Automatic Chemistry Analyzer	PKL PPC115
Semi Automatic Chemistry Analyzer	PKL PPC210
Semi Automatic Chemistry Analyzer	PKL PPC218
Semi Automatic Chemistry Analyzer	PKL PPC220
Automatic Chemistry Analyzer	PKL PPC125
Automatic Chemistry Analyzer	PKL PPC200
Automatic Chemistry Analyzer	PKL PPC200N
Automatic Chemistry Analyzer	PKL PPC200U
Automatic Chemistry Analyzer	PKL PPC300
Automatic Chemistry Analyzer	PKL PPC300N
Automatic Chemistry Analyzer	PKL PPC300U
Automatic Chemistry Analyzer	PKL PPC400
Automatic Chemistry Analyzer	PKL PPC400N
Automatic Chemistry Analyzer	PKL PPC400U
Automatic Chemistry Analyzer	PKL PPC700

Salerno, 08 January 2019



Dr. Raffaele Pisanti
CEO