

First Romanian rapid tests manufacturer!



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DECLARATION OF CONFORMITY

According to essential requirements of the Directive 98/79/EC for in vitro diagnostic medical devices, of the European Council, the

Manufacturer

Camp Medica Distribution SRL

No. 29 Stanei Street, Sector 4, Bucharest - Romania

declare under our sole responsibility that the following IVD medical device,

Product name

See Now in vitro diagnostic rapid tests - see Annex 1,

meet the provisions of the European Directive 98/79/EC, concerning in vitro diagnostic medical devices, which apply to them.

Requests

European Directive no. 98/79/CE from October 27th, of the European Parliament Council for in vitro diagnostic medical

devices

Classification

medical devices for in vitro diagnostic (IVDD)

EDMA Code: see annex I

The following standards were used to prove the products conformity with the essential requirements of the above directive: **SR EN ISO 13485:2012.**

Standards Applied

EN 375: 2001, EN 980: 2008, EN 13612: 2002, EN 13640:2002, EN 13641:2002, SR EN ISO 14971:2012, SR EN ISO 13485:2012

• Place, Date of Issue Bucharest - Romania, 01.11.2016

Quality Manager
Dr. Eng. Carolina Constantin

