CAMP medica group

First Romanian rapid tests manufacturer !

MC Management Certification
Nr. certificat : 1002
ISO 13485:2012

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CE

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