CAMP MEDICA DISTRIBUTION RO16768740
Phone/fax : +4-021- 450.58.90/+4-0372892487
e-mail: export@campmedica.ro
http : //www.campmedica.ro

Nr. certificat : 1002
ISO 13485:2012

DECLARATION OF CONFORMITY

According to Annex III of the Directive 98/79/EC for in vitro diagnostic medical devices, of the European Council, we

- **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
- **Conformity assessment route** — Annex III (from European Directive 98/79/CE), sections 2 to 5
- **Classification** — medical devices for in vitro diagnostic (IVDD)
  EDMA Code : see annex 1

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, 20.01.2017

Quality Manager
Dr. Eng. Carolina Constantin

Annex 1 – See Now Urine strips rapid tests

CE

CODE	Product name	EDMS code	Risk Class
Clinical Chemistry			
SN 13.1	**See Now** Urine strips - 10 parameters	**11 70 02 02 00**	**Low Risk**
SN 13.2	**See Now** Urine strips - 11 parameters	**11 70 02 02 00**	**Low Risk**
SN 13.3	**See Now** Urine strips - 12 parameters	**11 70 02 02 00**	**Low Risk**
SN 13.4	**See Now** Urine strips - 13 parameters	**11 70 02 02 00**	**Low Risk**

Quality Manager
Dr. Eng. Carolina Constantin