



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 SRL**
Str. Vultureni nr. 80, Sector 4, Bucharest – Romania

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

- ◆ **Product name** **See Now Troponin I test**

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 : 15 70 01 05 00

The following standards were used to prove the products conformity with the essential requirements of the above directive: **SR EN ISO 13485:2004.**

- ◆ **Standards Applied** EN 375: 2001, EN 980: 2003, EN 13612: 2002, EN 13640:2002, EN 13641:2002, SR EN ISO 14971:2007, SR EN ISO 13485:2004
- ◆ **Place, Date of Issue** Bucharest – Romania, 05.01.2011

Quality Manager
Dr. Eng. Carolina Constantin