

# EC 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 HBsAg test – (Hepatitis B surface antigen 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

◆ **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