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Nr. certificat : 1009  
ISO 13485:2016**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 devices,

♦ **Product name** **See Now** in vitro diagnostic rapid tests – see Annex I,

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 13485:2016**.

♦ **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 13485:2016

♦ **Place, Date of Issue** Bucharest – Romania, 22.01.2018

**Quality Manager**

Dr. Eng. Carolina Constantin

