



## Simple Simon® PT Plus Declaration of Conformity



**ZAFENA AB**  
Norrbygatan 1  
59031 Borensberg  
Sweden

Declare under our sole responsibility that the product  
**Simple Simon®PT and Simple Simon® PT Plus**

To which this declaration relates is in conformity with the following standards:

EN 60601-1-2:2007, guidelines for the safety of medical electrical equipment;  
emission.

EN 60601-1-2:2007,

EN 61000-4-2,-3,-4,-5,-6,-8,-11, guidelines for the safety of medical electrical  
equipment; immunity.

EN 375. Information supplied by the manufacturer with in vitro diagnostic reagents for  
professional use.

EN 23640: Stability testing of in vitro diagnostic reagent.

EN 13641: Elimination or reduction of risk of infection related to in vitro diagnostic  
reagents.

Following the provisions of Annex I of the Directive 98/79/EC on *in vitro* diagnostic  
medical devices.

The conformity was established by the manufacturer in a conformity assessment  
procedure according to Annex III of the Directive 98/79/EC, except of point 6.

ZAFENA AB  
Borensberg 2019-10-03



Marie Danielsson-Rånby, Quality manager