EU Declaration of Conformity

1. **Name and address of the manufacturer**

   Te?ted Oy
   Mattilanniemi 6-8
   FI-40100 JYVÄSKYLÄ
   info@tezted.com

2. **This declaration of conformity is issued under the sole responsibility of the manufacturer.**

3. **Object of declaration:**

   IVD Device/Brand name: Tickplex®
   Model: Plus

4. **The object of declaration described above is in conformity with the relevant legislation:**

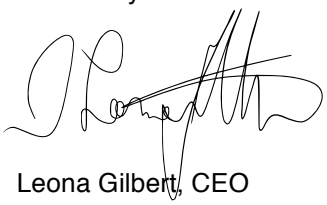
   - In vitro diagnostic medical devices directive (98/79/EC).
   - Finnish medical devices act (629/2010).

5. **Reference to the relevant harmonised standards used of references to the other technical specifications in relation to which conformity is declared:**

   - SFS-EN ISO 14971 Medical devices. Application of risk management to medical devices.
   - SFS-EN 13612n + AC Performance evaluation of in vitro diagnostic medical devices.
   - SFS-EN ISO 23640 In vitro diagnostic medical devices. Evaluation of stability of in vitro medical reagents.
   - SFS-EN ISO 18113-1 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1: terms, definitions and general requirements.
   - SFS-EN-ISO 18113-2. Part 1: terms, definitions and general requirements.
   - SFS-EN 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information supplied. Part 1: General requirements.

6. **Signed for and behalf of:**

At Jyväskylä __12__ of June 2017
Manufacturer:
Te?ted Oy



Leona Gilbert, CEO