



**OU InterVacTechnology**  
Kadastiku 57, Narva, Estonia

Reg. № 63 /15 from 23.10.2015

**To whom it may concern**

**DECLARATION**

We, InterVacTechnology OÜ, Kadastiku 57, Narva 21004, Estonia, hereby declares that:

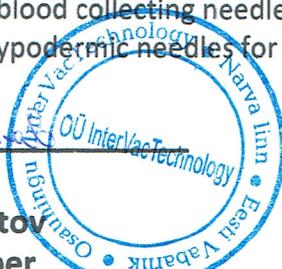
Lind-Vac® blood collecting needles are medical devices of class IIa following the European Medical Device directive MDD 93/42/EEC. The Lind-Vac® needles are CE marked following the conformity assessment procedure set out in Annex II of the Medical Devices Directive. The related certificate has been issued by the Notified Body. TÜV SÜD Product Service GmbH (0123).

Lind-Vac® blood collecting needles are sterilized following a validated sterilization method and released in routine in accordance with the requirements specified in EN 550 "Sterilisation of Medical Devices: Validation and routine control of ethylene oxide sterilization". The products are in compliance with the requirements regarding sterility specified in ENN 556-1 "Sterilization of Medical Devices: Requirements for medical devices to be designated "sterile" – Part 1: Requirements for terminally sterilized medical devices".

Lind-Vac® blood collecting needles are intended for single use and are available for multiple sampling.

The geometry of the needle point of the Lind-Vac® blood collecting needles complies with EN ISO 7864 "Sterile hypodermic needles for single use".

The Lind-Vac® blood collecting needles are colored coded in accordance with the specifications of ISO 6009 "Hypodermic needles for single use – Color coding for identification".

  
  
**Maxim Fedotov**  
**Board member**

**23.10.2015**