**The statutory declaration accompanying an application for an entry of the veterinary technical device into register of veterinary technical devices**

*………………………………. (name of the device)*

The applicant for an entry of veterinary technical device *…………. (Applicant’s identification data)* represented by

Authorised person *………… (Authorised person identification data)* declares hereby:

* that the manufacturer of the device complies with the principles of quality assurance   
  of manufacturing by following the principles set out in good manufacturing practice as described in the relevant production standards and guidelines (ISO, GMP) and has processed in writing, implemented and adhered to system procedures of Hazard Analysis and Critical Control Points (HACCP); that the raw materials used for manufacturing of the device are not of ruminant origin; (or if so, an evidence that the animals were free from BSE / TSE should be provided),
* that the device is suitable for the veterinary use, and is fit to achieve the intended purpose   
  if used according to the Instructions in the package leaflet,
* that the device, including the packaging material, has been assessed for safety and is safe   
  for animal health and for the health and safety of persons handling it, for property and the environment,
* that, provided that the prescribed storage conditions and handling of the device are observed, the device is stable and retains its declared composition and characteristics for its entire intended shelf life.

In………..……, Date…….………. ..……….…………………………………………………………

Signature of the applicant or authorised person