

- Quality Manual (in English).
- Risk management report (in English).
- Pre-clinical evaluation report (in English).
- Clinical evaluation report (in English).
- Validation of sterilization (report) (if applicable, in English)
- Draft of the label for Ukrainian market (in Ukrainian)
- Draft of instruction for use (in Ukrainian)
- Draft of declaration of conformity (in Ukrainian)
- Agreement between manufacture and authorized representative in Ukraine.
- Essential requirements checklist according to TR (form of it is in attachment for this letter).