**Sterility Test**

**Application field**
The sterility test is used to determine if a medical device is sterile.

**Interests**
Manufacturers are requested to demonstrate the sterility of their products. Product items produced under standard manufacturing conditions in accordance with the requirements for quality systems for medical devices may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such product items are nonsterile. The purpose of sterilization processing is to inactivate the microbiological contaminants and thereby transform the nonsterile items into sterile ones.

**Principle of the test**
A sterile product item is one which is free of viable microorganisms. A nonsterile device burdens microorganisms on it and these can easily grow in an appropriate culture medium at an appropriate temperature.

**Test procedure**
The method of performing the test of sterility can be broadly divided into two general categories:

**Direct immersion of product:**
direct immersion is the preferred method of performing the test of sterility for medical devices. With direct immersion, the product unit or SIP (defined part of a medical device product that is tested) is placed aseptically into a container of growth medium and incubated. A sufficient amount of growth medium should be used to achieve contact between the growth medium and the whole of the product unit or SIP.

**Removal of microorganisms from product:**
when it is not possible to use direct immersion due to the characteristics of the medical device, such as bacteriostatic/fungistatic activity, employing removal of microorganisms might be necessary.

At the end of the incubation period, media is examined for macroscopic evidence of microbial growth. If no evidence of microbial growth is found, the product to be examined complies with the test for sterility. If evidence of microbial growth is found the product to be examined does not comply with the test for sterility, unless it can be clearly demonstrated that the test was invalid for causes unrelated to the product to be examined.

**Normative references**
- EN ISO 11737-2:2009
- E.P. 7th edition <2.6.1>
- USP 34–NF 29 <71>

**Exclusion from test**
The normative EN ISO 11737-2:2000 is not applicable to:
- sterility testing for routine release of product that has been subjected to a sterilization process,
- performance of a pharmacopoeial test for sterility,
- culturing of biological indicators, including inoculated products

**Expression of results**
Pass/Failed – Sterile/Non sterile
In case of contamination, the evaluation of microbial contamination can be performed.

**Turn around time**
3 weeks.

**Number of products/Quantity necessary to the analysis**
The number of products necessary to the analysis depends on the aim of the sterility test. For routine control usually 20 samples are required.