Hygiene standard of our disposable products:

“Sterile, aseptic, clean etc”: It can be difficult to describe the sanitary level of our products by means of the usual terms and standard definitions, when they exist. As a result, we have drawn up this document to clarify these concepts in the light of our knowledge and the current legislation.

OFFICIAL DEFINITIONS

There is only one normative definition to date: the concept of sterility. The word “sterile” is defined in the standards EN 556-1 and EN 552. According to standard EN-556-1, sterile is “the condition which is free of viable micro-organisms.” Standard EN 552 specifies that “the inactivation of a micro-organism culture by the physical or chemical agents used for sterilisation can frequently be represented by an exponential law; inevitable, this means that there is finite probability that a micro-organism will survive, regardless of the effectiveness of the treatment used.” “The sterility of a given product must be defined in terms of the probability of the survival of micro-organisms.” EN 556-1 states that “in order for a medical device to be labelled as sterile, the probability that a viable organism is presented on the device must be less than or equal to 1 x 10^-6, i.e. a SAL(1) greater or equal to 6.”

nerbeplus DEFINITION:

nerbeplus has created a classification hierarchy for its products based on the production methods, the manufacturing environments and the risks associated with the products’ uses. Backed up by more than 30 years of experience and in line with the company’s strategy of closely paying attention to its clients, we have defined 5 sanitary level categories: STERILE, IONISED, ISO5 ASEPTIC, ASEPTIC and CLEAN. A symbol matching each of these categories and based on the official symbols described in the ISO 15223 and EN 980 standards has been created. This symbol is shown in the products insofar as this does not hinder their use.

STERILE

Symbol: STERILE R
Sanitary risk: SAL ≥ 6 (normative)
Example of products: Petri dishes – Swabs

Sterile products have undergone a sterilisation treatment after production in their final packaging using β radiation. This means that they are bombarded with electrons to break down macromolecules, including DNA, and this destroys all microbial life forms. For a product to be classified as sterile, we must be in a position to guarantee a SAL of 6.

To do this, we check that the bioload before sterilisation is low and that the destructive capacity (DRR, Decimal Reduction rate) of the electron beam is at least 106 times higher than the initial bioload. The two checks combined guarantee a STERILE product by parametric release for each sterilisation batch. The official symbol is STERILE R. The “R” means that sterility was obtained through the use of radiation.

Note: there are other methods of sterilisation, including treatment in an autoclave or treatment by ethylene oxide (STERILE EO). We are currently seeing the limitations of this latter process due to appearance of allergies caused by ethylene oxide residues accidentally present in the products that were sterilised using this method.
IONISED

Symbol: ![IONISED]

Sanitary risk: SAL $\geq 6$
Example of products: Sampling containers – Spreaders – Flasks

The process for ionised products is almost the same as for sterile products. The only difference is that we do not know the initial bioload. Therefore, it is not legally possible to guarantee the sterility of the products from a normative point of view. Nevertheless, research and our experience have shown that there are no problems associated with the use of an ionised product in a demanding sanitary environment. The majority of our products are treated at 10 Kgray. At this dosage, we have shown a logarithmic decrease of 10 to 13. This means that we can destroy from 1010 to 1013 of the initial bioload. The production method used by nerbe plus involves the fusion of raw materials at temperatures in excess of 200°C. In any case, the initial bioload is very low.

Note: STERILE and IONISED products carry a label with an ionising treatment indicator. This is a label stating all the traceability information as regards both manufacturing and sterilisation. The centre of the label is detachable and can be used as a certificate. In this way, the end users can paste the certificate onto a logbook instead of laboriously copying out the codes and references.

ISO 5 ASEPTIC

Symbol: ![IONISED]

Example of products: Petri dishes

ISO5 Aseptic products are produced in an ISO 5-class filtered and monitored atmosphere (Class 100). This involves the use of an automated machine, almost without any human intervention, which is placed in a closed-off environment where the air is filtered by class-100 filters. These facilities are themselves placed in workshops where the air filtering in class 100 000 (ISO 7). The purpose of the facility is to limit product recontamination before packing in airtight packaging. In fact, there is no contact outside of the air-filtered area from the point of fusion of the materials at 250°C until the products are packed in sealed bags. As a result of our strict production conditions and the numerous checks we carry out (for particles and microbiological contamination) the SAL at the end of the production line is between 4.7 and 5.

Note: the concept of STERILE A (A as in aseptic) does not apply to our products. This refers solely to a laminar flow technique for pouring medicinal liquids into containers that are initially sterile. In this case, the concept of Aseptic should not overshadow the word STERILE, which predominates. The final product must have a minimum SAL of 6.

ASEPTIC

Symbol: ![ASEPTIC]

Sanitary risk: SAL $\geq 3$ to $4$
Example of products: test tubes, sampling containers with cap

ASEPTIC products are produced on machines whose at-risks areas have been closed off. The production method for plastic products requires the materials to be fused at temperatures in excess of 200°C. Our organisation allows us to close the container immediately after it is ejected from the mould. The recontamination time when the product is still open is very short and closed conveyors are used for transfers. The average SAL obtained is in the region of 3 to 4. The recommended use of these products is for non-microbiological testing.
CLEAN

Symbol: None

Sanitary risk: SAL ≤ 3
Example of products: sampling containers with spatula – manual series – autoclavable bagging

CLEAN products are manufactured on machines which use manual removal. This classification covers only a very limited portion of our range designed for low-level sanitary applications. With manual intervention and without a post – production sterilisation treatment, it is not possible to guarantee a specific sanitary level. The results of our testing place the SAL in the region of 3. The recommended use of these products is for non microbiological testing.

Note: the company regularly conducts hygiene awareness campaigns for its staff and offers training for personnel in the use of the products.

Discontinued model

The following table summarizes the principal recommendation for the use of our products according to their sanitary level. The classification takes into account the risk of interference on quantative research by enumerations and for qualitative research. Qualitative Analysis: without enumeration, for insulation and microbiological identification (on selective medium).

<table>
<thead>
<tr>
<th>USES</th>
<th>sterilR</th>
<th>ionised</th>
<th>aseptic ISO 5</th>
<th>aseptic</th>
<th>clean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyse without microbiological character</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>rein</td>
</tr>
<tr>
<td>Microbiological analysis with high suspected (105 CFU)</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Microbiological analysis with medium suspected microbial level (105 CFU)</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>X</td>
</tr>
<tr>
<td>Microbiological analysis on very selective media (pathogenic research: Salmonella, etc.)</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>X</td>
</tr>
<tr>
<td>Microbiological analysis with long incubation</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>O</td>
<td>X</td>
</tr>
<tr>
<td>Microbiological analysis on non selective media with suspicion of low microbiological level (pasteurisation control)</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Semi quantitative Analysis</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Qualitative analysis without enumeration, for microbiological identification (on non selective media)</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Qualitative analysis without enumeration, for microbiological identification (on non selective media)</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>X</td>
</tr>
</tbody>
</table>

R = Recommended
O = Possible (according to the nature and the methods of analysis)
X = Non recommended