Hygienic classes for process valves

A guideline for users

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Hygienic classes for process valves

Customers of process valves evaluate suitable solutions for complex production requirements. To better assist them, GEA has set up this brochure as a guideline for choosing the right hygienic component technology.

Increasing variety of products, longer production cycles, and changing market conditions are all factors that make the conception of new installations more complex for producers. Additionally, there are higher expectations from the consumers as well as stricter regulations for producers and products. Therefore, the engineers have many things to consider when creating suitable solutions for their customers.

The association of German Food Processing Machinery and Packaging Machinery (VDMA) has, especially in the field of filling technology, established useful guidelines for the industry. The concept of the hygienic classes enables to select machines with the appropriate hygienic characteristics to meet specific product requirements. GEA Flow Components utilizes this hygienic classification concept with process components, starting with valves.

As known from the VDMA, components are classified into hygienic classes I–V; from Hygienic (I–III) and UltraClean (IV) to Aseptic (V). For filling machines, the disinfection rate of the sterile area and the packaging material are critical factors. Contamination risks and being able to detect these risks are necessary factors with component design. In both of these areas, the classification is based on the desired characteristics of the final product.

This brochure is meant to be a practical introduction to hygienic classes and hygienically classified valve concepts, with microbiological contamination risks taken into consideration. GEA Flow Components has more than 80 years of experience in valve technology, over 30 years of experience in aseptic technology, and a portfolio that also contains hygienic pumps and tank cleaning equipment. The ultimate goal is to equip your installation with tailor-made components for your product and your market.

Don't hesitate to contact us with your questions. We will gladly discuss your application requirements, components and suitable solutions.

Microbiology defines the classification

The hygienic classes can be described through microbiological, physicochemical as well as the resulting organoleptic properties. An important indicator for the classification of the product is its shelf-life.

The defined shelf-life is characterized primarily through the microbial stability of the product and through the planned logistical chain of distribution. The table (see page 5) is a guide of how the hygienic classes Hygienic, UltraClean and Aseptic can be derived. From the parameters shown in the table, a single parameter can shift a product/process from one class into the other with borders being gradual.

An important criterion is the type of food and its ability for being a substrate for micro-organisms. These are distinguished between pathogenic and non-pathogenic organisms. The latter do not have an immediate effect on the health of the consumer, but can nevertheless deteriorate the product. Taste, aroma and appearance are final factors consumers use to rate the producer and its brand. Taking the importance of product image into consideration, there is nothing more important to food manufacturing than product and process safety.

Microbial stability and hence shelf-life of a product is reached through a bacterial load reduction. This is a measured logarithmic reduction of cell count caused predominantly by direct or indirect heating processes. Applying this bacterial reduction step can only be done by knowing the relevant organisms with their specific heat resistance, measured in D- and Z-value. These two values are specific for microorganisms and can be influenced by the given food matrix, especially by proteins and fats. In addition, microorganisms can be found in different states and forms, e.g. vegetative or non-vegetative. This again will influence the ability to inactivate or kill the microorganisms within the foods and with the given process. The aim is to reach the cell count reduction, but at the same time, minimize the altering of the physicochemical, physiological or sensory properties of the product.

This is, as mentioned, usually achieved by classical heat treatment, sometimes combined with other unit operations, such as mechanical separation, electro-magnetic-induced forces or filtration. The process valves and components are an important part as well, as they can help avoid or minimize the risk of microbial contamination. This is already valid before the microbial load reduction, as the initial cell count is an important parameter for the reduction kinetics of microorganisms and, thus, for process and product safety and quality.

Parameter	Hygienic (I–III) / UltraClean (IV)	Aseptic (V)
pH-value	< 4.5	> 4.5
a_W-value	< 0.85	> 0.85
Minimum shelf-life	< 3 weeks	> 3 weeks
Distribution	chilled	ambient temperature
Preservatives	yes/no	no

The hygienic class “Hygienic”

The essential requirement for process components in direct contact with food is their hygienic design.

In order to fulfil the basic requirement of the Machinery Directive 2006/42/EC, the design has to be executed in a way which excludes any risk to personal health. Particularly, the materials used have to be cleaned before every use and the surfaces in contact with food shall not provide space for microorganisms to settle in, e.g. dents or edges. The background to this requirement is an irremissible demand to produce food safely and in a consistent quality with appropriate shelf-life.

Securing the implementation of a continuous, consistent and monitored process system is the key to reaching this high hygienic goal. In hygienic installations, this can be achieved with a cleaning process which is adapted perfectly to the product and the system. It puts the installation in a safe starting mode before every production. Components in the class Hygienic are designed to be completely and reliably cleaned as well as the connected piping system.

Often the differentiating factor between Hygienic components is not their cleanablility, but rather the effectiveness of it. The hygienic design of the component determines the required intensity of the cleaning process and thereby the use of the four parameters – the “Sinner circle” time, temperature, chemistry and mechanics to effectively clean the wetted product area of the valve. The availability of known certificates for components such as EHEDG, 3A, etc. further emphasizes the efficiency of cleaning. All of these certificates stand for hygienic design, and in the case of EHEDG, for the cleanability of the component compared to a reference pipe and standardized, monitored test conditions.

Components within the Hygienic class are used in various food and beverage industry applications, where requirements towards reducing germ load or maintaining the shelf-life of sensitive products have to be considered – noticeably in brewery, dairy, beverage and food production plants. Outside the food and beverage industry, hygienic components are found in pharmaceutical, healthcare, biotech, fine chemicals and cosmetics production facilities.

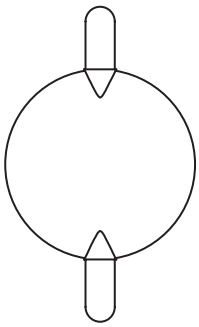
Hygienic components

Hygienic components distinguish themselves with the use of high-quality materials and the cleanability of all parts and surfaces in contact with product.

A hygienic component ensures thorough sanitation during cleaning of the piping system (CIP – cleaning in place) without needing to be disassembled.

Butterfly valves

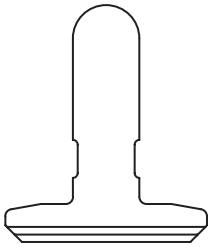
Butterfly valves are the most simple and common types of hygienic valves in the market. They are particularly popular because they are a cost-effective way to stop the product flow within the pipeline.



Microbiological contamination risk	Possible sources of failure	Possibility of detection
Product residues at shaft connection	Insufficient cleaning caused by bad sealing designs	none
Valve shaft sealing	Malfunctioning sealing at the shaft connection caused by high stress	Visual detection
Surface damages	High mechanical stress caused by occuring torsion forces	Conditional visual detection

Seat valves

Seat valves are used to shut off a pipeline. Compared to butterfly valves, the sealing design of seat valves provides less product wetted sealing surface, torsion-free activation and a defined swaging of the seal while the valve is closed. Furthermore, seat valves (such as mix-proof valve technology) can separate connected pipelines and therefore lead to increased productivity.



Microbiological contamination risk	Possible sources of failure	Possibility of detection
Elevator effect	Microorganisms seated on the valve stem are brought into the product area while activating the valve	none
Contamination behind seals	Badly designed sealing concepts can lead to contamination behind a product wetted seals	none

The hygienic class “UltraClean”

The hygienic class UltraClean is originated from the classification of filling machines with food-producing companies. The class is defined particularly through the targeted properties of the final product.

Shelf-life is the most relevant product parameter. It is mostly determined by the pH-value and the a_W-value of the product. In addition, sensory properties need to be considered as well as the logistical chain of distribution. One of the advantages of UltraClean processing is the reduced quantity of preservatives needed for maintaining the shelf-life of the product.

UltraClean valves are commonly used for dairy-based sour-milk or ESL milk products. A low pH-value of the product or a constant cooling-chain, in combination with UltraClean components, provides an improved product quality with longer shelf-life.

Other important applications for UltraClean processes are fruit juices and other fruit-based drinks. Again, the pH-value of the product is a key indicator. When the known pH is below 4.5, the use of UltraClean components is recommended.

Moreover, water-based drinks (juice, beer, tea, coffee) are potential products for UltraClean components. The rapidly growing product categories of sports and wellness drinks, as well as premium food products, are eligible for this hygienic class. In addition, dressings and gravies are also suited for UltraClean processes. UltraClean components can, of course, serve as an upgrade to any traditional hygienic process, e.g. in the brewing industry.

Generally speaking, non-dairy products qualifying for UltraClean applications and technology can allow repeated heat treatment as long as the final product quality falls within an acceptable range. For more sensitive products, which cannot go through a thermal treatment more than once, aseptic processes and components might be more suited.

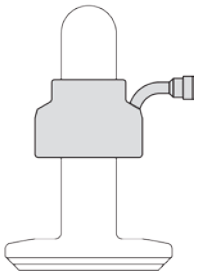
UltraClean components

UltraClean valve components are characterized by a higher safety protection against contamination from the environment and, thus, warrant microbial stability of the product over the whole process.

The increased safety of UltraClean valves is mainly described by the protection of the valve stem against the atmosphere – either by steam or by a hermetical sealing diaphragm. The same design rules for Hygienic-class valves used with foods apply for UltraClean components.

Valves with sterile lock

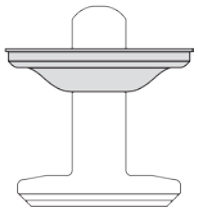
The sterile lock can be mounted on existing hygienic valves in order to upgrade these installations to UltraClean processes. In this concept, the valve stem is protected by a steam barrier. Generally, this only allows a steaming of the interface to the atmosphere. Normally, there is not an enclosed system to allow sterilization temperatures, this is why the solution cannot be seen as equally safe as a hermetical sealing of the valve stem.



Microbiological contamination risk	Possible sources of failure	Possibility of detection
No sterilization of valve stem	· No active steam circulation end, thus no sterilization	none
Valve stem sealing	· No permanent steam barrier recommended (life time of the seal, product burn-ons) · Unintentional inoculation of the product with contaminated condensate	none
Loss of steam barrier	· Power loss · Problems with steam production	Temperature monitoring

Diaphragm and stem diaphragm

Both diaphragm and stem diaphragm valves are well known in the industry. Normal diaphragm valves are usually used in pharmaceutical processes; stem diaphragm valves, on the other hand, are frequently used in food-related applications. The diaphragm is sealing the product area hermetically against the atmosphere. Accordingly, this valve type complies with the requirements of aseptic processes. Due to the limited detection possibilities of the diaphragm material and the dynamically stressed fixation points between stainless steel and synthetic material, GEA primarily classifies the diaphragm technology as UltraClean.



Microbiological contamination risk	Possible sources of failure	Possibility of detection
Membrane deformation	· Occuring blisters because of unfavorable sterilization cycles	none
Surface damage	· Micro scratches · Insufficient heat transfer caused by low heat conductivity of the material	none
Dynamically stressed fixation points	· Undefined conditions at seal fixation points (e.g. temperature influences) · Detachable connection in product area	Conditional visual detection
Hollow space in the membrane	· Composites (e.g. multi-layer membrane)	none
Cracked membrane	· Fatigue fracture · Precedent membrane deformations / surface damages · Hydraulic or thermal pressure hammer	Visual detection

The hygienic class “Aseptic”

In the Aseptic class the emphasis is on commercial sterility and prevention of microbiological contamination after sterilization.

For aseptic processes, the following areas have to be considered: Product sterilization, conveying and maintaining sterility, and filling under sterile conditions. Aseptic processes signify high-quality products and/or long shelf-life, produced for specific consumer groups. Besides classic UHT milk products, medical nutrition and baby food also belong to this hygienic class.

Product sterilization

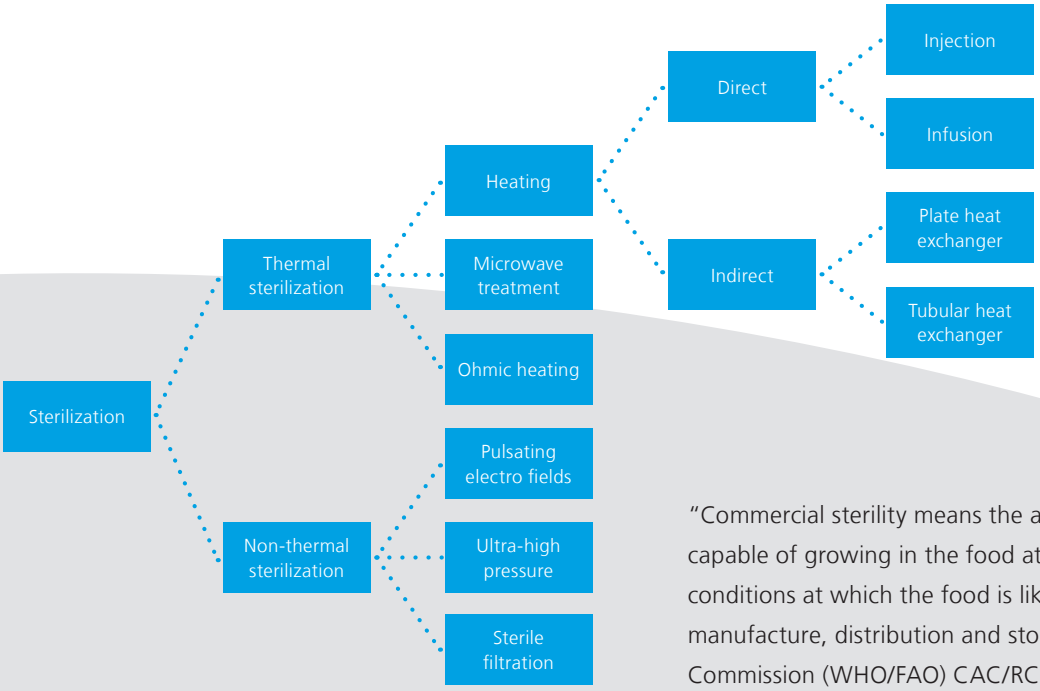
The sterilization of a product can be achieved with different processes. The diagram gives a general overview. There are always ambitions to combine processes based on the “hurdle concept”, in order to achieve a gentle treatment with high quality products and while maintaining ideal sterile conditions. Generally speaking: The more valuable the product and the more heat-instable the food matrix, the more complex are the technologies applied in the process, from the components used up to sterilization and filling methods.

Maintaining sterility

In order to keep a product sterile, the installation needs to be highly automated and always kept in a defined overpressure. Furthermore, the installation has to be perfectly cleaned and sterilized in-place. If the product gets stored in a tank before filling, the tank needs to be maintained under pressure by means of sterile gas. Aseptic process components greatly contribute to the aseptic operation of an installation.

Sterile filling

Aseptic product filling is complex field and takes various criteria into account. Nevertheless, any aseptic filling machine must fulfill several factors: In the area of the filling valves, the machine must operate in clean-room conditions with filtered air, and a laminar flow against the container filling direction has to be ensured. In-place cleaning and sterilization complete the basic criteria. To ensure aseptic filling across the production chain, the container and cap of a commercially sterile product must be pre-sterilized and kept sterile until the final hermetic seal.



“Commercial sterility means the absence of microorganisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.” Codex Alimentarius Commission (WHO/FAO) CAC/RCP 40-1993

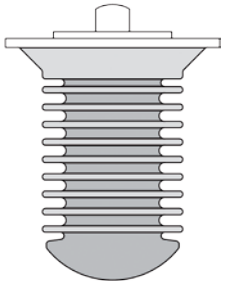
Aseptic components

Aseptic valves distinguish themselves with the uncompromisingly hermetic seal of the valve stem, thereby minimizing contamination risks.

In contrast to the lower hygienic classes, a hermetic seal of the product area against the environment (atmosphere) is mandatory with aseptic components. With this mandate, contamination risks are lower than when compared with components from other classes. Aseptic components have the highest ranking in part due to detection possibilities, particularly by using stainless steel bellow technology. Aseptic components are subject to continuous sterilization cycles and therewith to changing temperatures occurring in the installation.

PTFE bellow

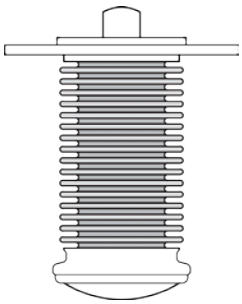
Valves equipped with PTFE bellows are well known in the aseptic market. The main difference between PTFE and stainless steel bellows is their possibility of failure detection. Other than with stainless steel bellows, and similar to the diaphragm/membrane technology, a deformation and/or partial damage of the hermetic seal is more likely to occur than a full crack. In contrast to the diaphragm/membrane, this valve concept does not include dynamically forced sealing connections, and due to the fabrication method the risk of blistering is considerably reduced.



Microbiological contamination risk	Possible sources of failure	Possibility of detection
Bellow deformation	· Flow combined with high temperature · Cold flow in the seat area · Valve activation during sterilization · Hydraulic, thermal or mechanical pressure hammer	none
Surface damage	· Micro-scratches · Insufficient heat transfer caused by low heat conductivity of the material	none
Cracked bellow	· Fatigue fracture · Precedent bellow deformations / surface damages · Hydraulic, thermal or mechanical pressure hammer	Visual detection

Stainless steel bellow

Aseptic valves with stainless steel bellows are considered the highest class of aseptic valves. This is due to the material and the permanent joint at both sides of the bellow, as well as the bellow monitoring in the process.



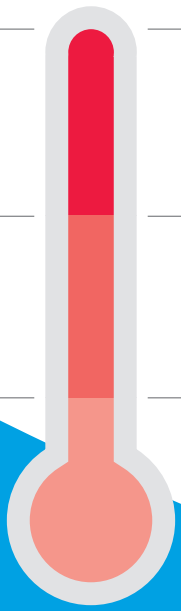
Microbiological contamination risk	Possible sources of failure	Possibility of detection
Cracked bellow	· Fatigue fracture · Hydraulic, thermal or mechanical pressure hammer	· Visual Detection · Optional via temperature with steam barrier · Optional via level with liquid, sterile medium

The right valve for every process

The selection of the right valve technology is based on well-founded knowledge about products and processes. Aside from target group and consumers, other influencing factors play a role in product characteristics, including transport and storage.

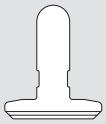
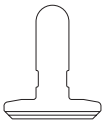
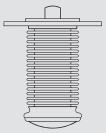
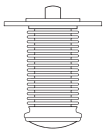
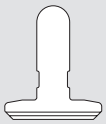
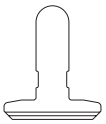
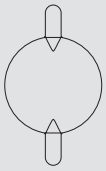
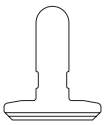
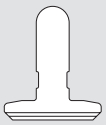
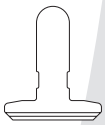
It is clear, for the ideal valve technology the respective process has to be taken into account with each new installation. The chart on the opposite page shows listings of typical products for the three hygienic classes. They are examples to assist in the initial decision-making process. The valve symbol depicted shows the minimum component standard in the respective process step. An upgrade of components within an installation can be achieved by equipping process steps with valves of a higher hygienic standard than the recommended minimum.

Hygienic classes



Aseptic	Aseptic valves with metal bellows Aseptic valves with PTFE bellows
UltraClean	Stem diaphragm valves Hygienic seat valves with sterile lock
Hygienic	Hygienic seat valves Hygienic butterfly valves

VDMA hygienic classes:
I–III: Hygienic
IV: UltraClean
V: Aseptic

	Product	pH value	Distribution	Shelf-life	Component standard: Storage	Preparation	Preservation	Filling
Aseptic (V)	UHT milk UHT cream	> 4.5	ambient temperature	> 3 months				
	Ice tea (still)	> 4.5	ambient temperature	> 12 months				
	Soft drinks (still)	> 4.5	ambient temperature	several months				
UltraClean (IV)	Fruit juice	≤ 4.5	ambient temperature	several months				
	Ice tea (still)	≤ 4.5	ambient temperature	> 6 months				
	Fruit yoghurt heat-treated	≤ 4.5	ambient temperature	> 5 weeks				
Hygienic (I–III)	Fruit yoghurt	≤ 4.5	chilled	2–4 weeks				
	Beer	≤ 4.5	ambient temperature	> 6 months				
	Wine	≤ 4.5	ambient temperature	> 1 year				

Decision-making

The final hygienic classification of the components is, in every case, subject to further evaluations based on the requirement profile and weighing of characteristics, which are best known by the manufacturer. Aside from the aforementioned factors, possible follow-up costs including maintenance and monitoring efforts need to be considered, in order to ensure a continuous and safe production. As with all the other areas of an installation, process components have to be evaluated to identify the most accurate valve concept for the given properties. The resulting conclusion is partially fluent borders between the described hygienic classes; thereby the final classification can only be rated by the manufacturer of the product.

With an integrated product portfolio and our long-lasting experience, GEA Flow Components aims to provide present and future decision makers with guidelines and the right component technology for every process.

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a better world

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GEA is a global technology company with multi-billion euro sales operations in more than 50 countries. Founded in 1881 the company is one of the largest providers of innovative equipment and process technology. GEA is listed in the STOXX® Europe 600 Index. In addition, the company is included in selected MSCI Global Sustainability Indexes.

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