



CE mark 2006/42/EC

The pumps comply with the relevant essential health and safety requirements of the EU Machinery Directive 2006/42/EC.

The pumps are designed and manufactured in accordance with the following transposed harmonised European standards:

Type A standards:

BS EN ISO 12100, Safety of Machinery - Basic concepts, general principles for design,
 Part 1: 2003+A1:2009, Basic terminology, methodology. (Incl. amendment 14974 Jan 2004)
 Part 2: 2003+A1:2009, Technical principles. (Incl. amendment 14975 Jan 2004).

Type B standards:

BS EN ISO 13857:2008, Safety of Machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs.

BS EN 349:1993+A1:2008, Safety of Machinery - Minimum gaps to avoid crushing of parts of the human body.

Other standards:

BS EN 287-1:2004, Qualification test of welders - fusion welding - Part 1: steels
 (including amendments 15598 February 2005, 16295 July 2006 & 16831 January 2007)

Qualified welders are used and they have been tested to this standard.

Optional standards

ATEX directive 94/9/EC

Equipment and protective systems intended for use in potentially explosive atmospheres. This EU directive entered in force on 01/03/96 and became mandatory from 01/07/03. It applies to all equipment (both electrical and mechanical) intended for use in potentially explosive atmospheres. Where ATEX is requested our pumps will normally be under Group II, Category 2 or 3.

Group II Other explosive atmospheres					
Category 1		Category 2		Category 3	
G (gas) (Zone 0)	D (dust) (Zone 20)	G (gas) (Zone 1)	D (dust) (Zone 21)	G (gas) (Zone 2)	D (dust) (Zone 22)
For equipment providing a very high level of protection when used in areas where an explosive atmosphere is very likely to occur		For equipment providing a high level of protection when used in areas where an explosive atmosphere is likely to occur		For equipment providing a normal level of protection when used in areas where an explosive atmosphere is less likely to occur	
Assessment: EC type-examination and Production QA / Product verification		Assessment: Internal control of production and send a dossier to a Notified body		Assessment: Internal control of production	

In addition to the standards used to comply with the Machinery Directive, the ATEX pumps have been designed and manufactured in accordance with the following transposed harmonised European standards:

BS EN 13463-1:2009, Non-electrical equipment for use in potentially explosive atmospheres
 Part 1: Basic method and requirements

BS EN 13463-5:2003, Non-electrical equipment intended for use in potentially explosive atmospheres
 Part 5: Protection by constructional safety "c"

ATEX pumps fully comply with the directive, and will be supplied with a compliant motor, ATEX label, ATEX certificates of conformity, and ATEX instruction manual.

The ATEX technical dossier (AT01) has been filed with Baseefa (2001) Ltd in Buxton, Derbyshire.

BS EN 13951: 2003, "Liquid pumps. Safety requirements. Agrifoodstuffs equipment. Design rules to ensure hygiene in use".

This standard applies to liquid pumps and pump units operating with agrifoodstuffs. It is NOT intended to be used for pumps handling pharmaceutical products. The standard aims to ensure that the pump if used in accordance with the instruction handbook, will remain safe and, provided it is adequately cleaned, will not cause contamination of the product. Note: due to the influence of the product, the process and the cleaning regime adopted, the hygiene of the pump should ultimately be the responsibility of the end-user.

The standard makes reference to BS EN 1672-2:1997 Food processing machinery - Basic concepts, Part 2 Hygiene requirements.

BS EN 13951 is one means of complying with the specific essential requirements of the Machinery Directive.

We need to request specific information at the time of quotation:

- Cleanability level required - levels 1, 2, 3 or 4 (see table below) - the level selected should take into account the risks arising from the pumped product, the placement of the pump in the process and the cleaning regime anticipated.
- If abrasive fluids are pumped (eg crystalline or fibrous foodstuffs), then the possibility of abrasive wear needs to be discussed and the choice of materials agreed.
- Surface finishes - the cleanability depends of the topography of the surface (profile, roughness), local fluid velocities, pump type, application and cleaning process. What is required depends on the pump application, eg the product itself (viscosity / effective viscosity and tenacity of residues) and where the pump is in the process (ie handling of raw, semi-processed or final product). We recommend 0.8µmRa for our pure finish.
- Connections - the customer will select the most appropriate connection having considered the hazards which may arise from their selection, installation and operation. Retention of product may be due to misalignment, physical change from thermal or chemical effects, incorrect installation (over or under tightening, omission of parts), or gaps and cavities inherent in the design. Hazards can arise from forces and moments from the pipework, unscrewing or mechanical shocks.
- Seal types. The hygienic risk level depends on the pumped product and the seal type. Note that mostly the liquids will be "Low viscous", and therefore the risk with a single mechanical seal will be low or medium.

Level	BS EN 13951 clauses complied with	Soils visibility to the naked eye after in-plant cleaning	Level of micro-organisms remaining
1	5.1.1, 5.2.8 & 5.4	Soils visible	Not defined
2	All	Soils visible	Not defined
3	All	No soils visible	Not defined
4	All	No soils visible	Defined level

3-A

The American 3-A Sanitary standards are intended to safeguard public health. They ensure that dairy, food and other microbially sensitive products are protected from contamination; that all product contact surfaces can be cleaned in place or easily dismantled for manual cleaning; and that all product contact surfaces can be easily inspected to confirm cleaning effectiveness.

The name 3-A arose from the original 3 Associations who joined forces to formulate uniform standards for fittings in the 1920s.

The main relevant standard is:

02-10 Centrifugal and positive rotary pumps for milk and milk products, 01/2006

EHEDG - European Hygienic Equipment Design Group

The EHEDG is an independent consortium formed in 1989 to develop guidelines and test methods for the safe and hygienic processing of food. The group includes representatives from research institutes, the food industry, equipment manufacturers and government organisations in Europe.

They have developed a standard test procedure for assessing cleanability based on comparing the cleanability of a test item with that of a straight length of pipe with a surface roughness of 0.5µm Ra.

The CH range has been independently assessed to this in-place cleanability protocol.

Pressure Equipment Directive 97/23/EC

Implemented in the UK by:

SI 1999/2001 The pressure equipment regulations 1999. Effective 30 May 2002 onwards and

Amended by SI 2002/1267 The pressure equipment (amendment) regulations 2002

These regulations apply to pressure equipment such as vessels, piping (including heat exchangers), safety accessories (eg safety valves and bursting discs) and pressure accessories where the maximum allowable pressure is greater than 0.5 bar.

The regulations do not apply to our pumps and vent valves. Pumps are excluded and the volume of vent valves are too small.

Strainers, however could be treated as pressure equipment depending on the vapour pressure of the fluid, the fluid group (see below), the strainer volume and the maximum pressure. Although in practice this is unlikely to arise in most applications, it may occur if you will be using a strainer with Group 1 fluids or alternatively with Group 2 fluids but where the vapour pressure of the fluid at the maximum allowable temperature is greater than 1.5 bar absolute.

- Group 1 fluids are dangerous, ie explosive, extremely flammable, highly flammable, flammable (where the maximum allowable temperature is above flashpoint), very toxic, toxic or oxidising.

- Group 2 fluids are fluids not in Group 1.

Optional standards specifically for the pharmaceutical and bioprocessing industries

FDA, Food and Drug Administration

Typically in the pharmaceutical applications, there is a requirement for the materials used in the construction of the pump to be FDA approved. This applies to the wetted parts and includes the mechanical seal and static seals.

The Food and Drug Administration Department of Health and Human services publish their rules in Title 21 of the Code of Federal Regulations (CFR). The relevant sections are

Part 177 - Indirect food additives: polymers

Part 182 - Substances generally recognised as safe

Part 211 - Current good manufacturing practice for finished pharmaceuticals

ASME BPE-2007 Bioprocessing Equipment

This ASME (The American Society of Mechanical Engineers) standard is an American National Standard and is a revision of ASME BPE-2005. It is applicable to the design of equipment used in the bioprocessing, pharmaceutical, and personal care product industries, including aspects related to sterility and cleanability, materials, dimensions and tolerances, surface finish, material joining, and seals. Equipment refers to vessels, tanks, piping, tubing and related accessories such as pumps, valves and fittings. Bioprocessing is the creation of a product utilising a living organism.

The user needs to specify:

- Cleanability and sterility procedures [SD-3] (eg is the pump steam sterilised? [SD-3.2.2]).
- Surface finishes (see table below) [SD-3.3.1].
- Inlet and outlet connections [SD-3.7.3].
- Approval of any painted exterior surfaces (eg the motor - note: for uncrowled motors, unless otherwise specified, paint will not be FDA compliant) [SD-3.8 (m)].
- Whether the pump outlet connection is to be tilted at 45° to allow for full venting of the casing (the drain then has to be fitted in the lowest point) [SD-4.5.2 (f)].
- Whether there any special welding inspection, examination, testing and record requirements [MJ-7.2].
- Seal types and materials.
 - o When choosing a seal material, the end-user should consider the biocompatibility, cleanability, steam stability, low temperature flexibility, creep resistance, sealability, leak resistance, solvent resistance, lot traceability and other factors, depending upon the application requirements [SG-2.4].
 - o Seal intrusion category (for static seals used in ferrules and hygienic connections) [SG-2.4].
 - o Whether the seal supplier needs to certify compliance to this standard (ASME BPE) [SG-3.4.1].
 - o The end user shall supply the complete sterilisation procedure, cleaning procedure and passivation procedure (including methods, frequency and length of operation) [SG-3.1.5 to 3.1.7].

Surface designation	Ra, maximum μ -in	Ra, maximum μ m	Electropolished
S F 0	-	-	No
S F 1	20	0.51	No
S F 2	25	0.64	No
S F 3	30	0.76	No
S F 4	15	0.38	Yes
S F 5	20	0.51	Yes
S F 6	25	0.64	Yes

MHRA, Medicines & Healthcare Products Regulatory Agency - Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007

This is the seventh edition of the "orange guide" (named after it's orange cover).

European Commission - The rules governing medicinal products in the European Union

Volume 4 Good manufacturing practices - medicinal products for human and veterinary use, 1998 edition (revised in 2004, 2005 & 2008).

This is based on directive:

2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, and

91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

ICH Q7A

International Conference on Harmonisation - ICH Q7A Good Manufacturing Practice for Active Pharmaceutical Ingredients 2000

BS EN 12462, Biotechnology - Performance criteria for pumps. 1998.

This standard is applicable to pumps used in biotechnological processes, in which the release of micro-organisms should be limited or prevented for reasons of safety (ie micro-organisms are hazardous or potentially hazardous).

The pump shall be classified for leaktightness, cleanability and sterilizability.

Other pump related standards

The list above is not exhaustive, and we can also comply with various other standards. Please just ask.

There are also numerous other standards related to pumps, for example for the fittings, seals and motors; and numerous standards on testing of pumps, documentation and tolerances.