Pump standards

Issue 11, April 2016

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 12100:2010, Safety of Machinery - General principles for design – Risk assessment and risk reduction.

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, Qualification test of welders. Fusion welding. Part 1: steels
Qualified welders are used and they have been tested to this standard.

Optional standards

ATEX directive 2014/34/EU

Equipment and protective systems intended for use in potentially explosive atmospheres. This EU directive applied from 20/04/16, replacing directive 94/9/EC. 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 13463-5:2011, 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 13951:2012, 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 provides hygiene related requirements to prevent the pump causing contamination of the pumped product when used in accordance with the instruction handbook. Note: due to the influence of the product, the process and the cleaning regime adopted, it is only the end-user that can ultimately ensure hygienic conditions during operation.

This type C standard is a means of conforming to essential requirements of the New Approach Directive 2006/42/EC on machinery.

The standard makes reference to EN 1672-2:2005+A1:2009 Food processing machinery - Basic concepts - Part 2 Hygiene requirements.

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	5.2.1, 5.3.8 & 5.5	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:

02-11 Centrifugal and positive rotary pumps for milk and milk products, 07/2012

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 &
SI 2015/399 The pressure equipment (amendment) regulations 2015.

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-2014 Bioprocessing Equipment

This ASME (The American Society of Mechanical Engineers) standard is an American National Standard and was developed to aid in the design and construction of new fluid processing equipment used in the manufacture of biopharmaceuticals, where a defined level of purity and bioburden control is required. Equipment refers to vessels, piping, and related accessories such as pumps, valves and fittings. A bioprocess is used in the manufacture and / or purification of biopharmaceuticals or other biological materials, eg microbial fermentation, cell culture, tissue culture, blood, or milk fractionation.
ASME BPE-2014 was effective from 10/04/15 (6 months after publication).

Edition	Published	Pages (approx)
ASME BPE-2014	10/10/14	300
ASME BPE-2012	28/09/12	270
ASME BPE-2009	20/10/09	210
ASME BPE-2007	21/03/08	120
ASME BPE-2005	28/04/06	110
ASME BPE-2002	26/07/02	90
ASME BPE-1997	First edition	80

The user needs to specify:

- The pump service parameters and all conditions under which the seal may be expected to operate. These include, in addition to the service temperature and pressure, any parameters that may affect the seal performance [SG-3.1]. In particular, the owner / user shall supply the complete sterilization procedure, cleaning procedure and passivation procedure (including methods, frequency and length of operation) [SG-3.1.5 to 3.1.7].
  Will the pump be subjected to SIP (Steam In Place) ? [SD-2.3.1.1]
  The Application Data Sheet, form R-1 (Appendix R) can be used to communicate the service parameters.
- Surface finishes, metallic (see table below) [SF-2.4]. Only one SF designation allowed [DT-10.1].
- Pump connections [SD-3.1.1(b)].
- Pump containment level [SD-2.1].
- Where ferrite levels are deemed necessary, the owner / user shall specify required ferrite ranges [MM-5.1.4].
- Exterior design: for equipment located in clean areas, painted surfaces should have advance approval of the owner / user. All paint systems shall be FDA compliant [SD-2.4.4.2(m)]. Note: unless otherwise specified, the motor paint will not be FDA compliant.
- Whether the pump discharge connection is to be tilted at 45^{O} to allow for full venting of the casing (the drain then has to be fitted in the lowest point) [SD-3.3.2.2(h)].
- Whether there are any special welding examination, inspection and testing requirements [MJ-7].
- Seal types and materials.
  - Material selection remains the responsibility of the owner / user [SG-3.3.1(b)].
  - Selection of the proper mechanical seal is the responsibility of the owner / user [SG-2.3.2.1(b)].
  - Mechanical seal surface finish requirements for the process side [SG-3.3.2.4(4)].
  - For seals, any assembly lubricant is the responsibility of the owner / user [SG-3.3.1(f) & SG-3.3.2.4(10)].
  - Whether the seal supplier needs to provide a Certificate of Compliance to this standard (ASME BPE) [SG-3.4.1].
  - Seal intrusion category (for hygienic union seals) [SG-4.2].

Metallic process contact surfaces

Surface designation	Ra, maximum µ-in	Ra, maximum µm	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

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, 2011, 2013, 2014 & 2015).

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.