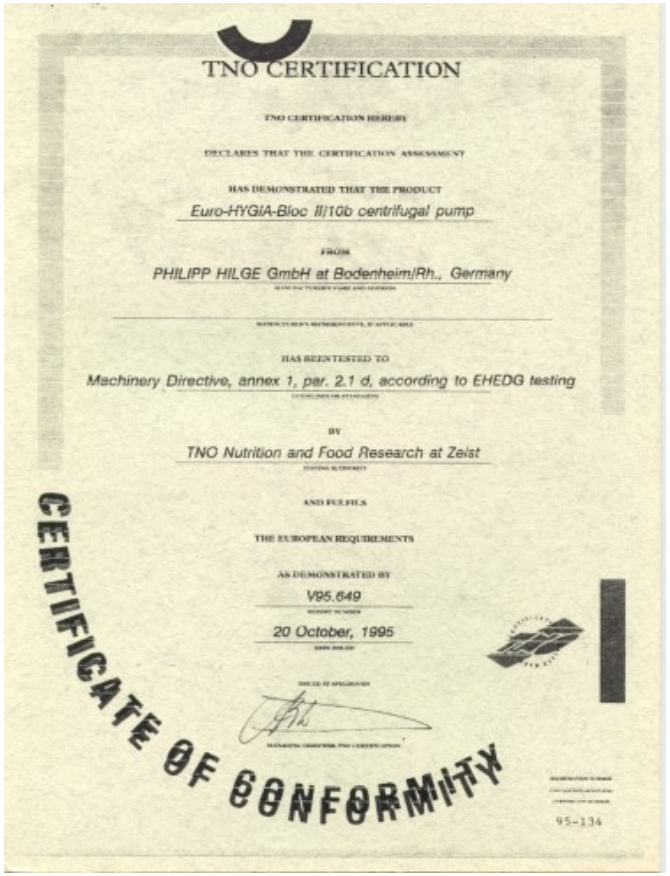
Dompensymposium 15/03/07

EHEDG Certification

EHEDG - European Hygienic Engineering & Design Group.

The highly regarded certificate for cleanability and hygienic design.

Awarded by TNO - the world recognised Dutch testing authority


TNO CERTIFICATION

TNO CERTIFICATION HEREBY

DECLARES THAT THE CERTIFICATION ASSESSMENT

HAS DEMONSTRATED THAT THE PRODUCT

Euro-HYGIA-Bloc II/10b centrifugal pump

FROM

PHILIPP HILGE GmbH at Bodenheim/Rh., Germany

HAS BEEN TESTED TO

Machinery Directive, annex 1, par. 2.1 d, according to EHEDG testing

BY

TNO Nutrition and Food Research at Zeist

AND FULFILS

THE EUROPEAN REQUIREMENTS

AS DEMONSTRATED BY

V95.649

20 October, 1995

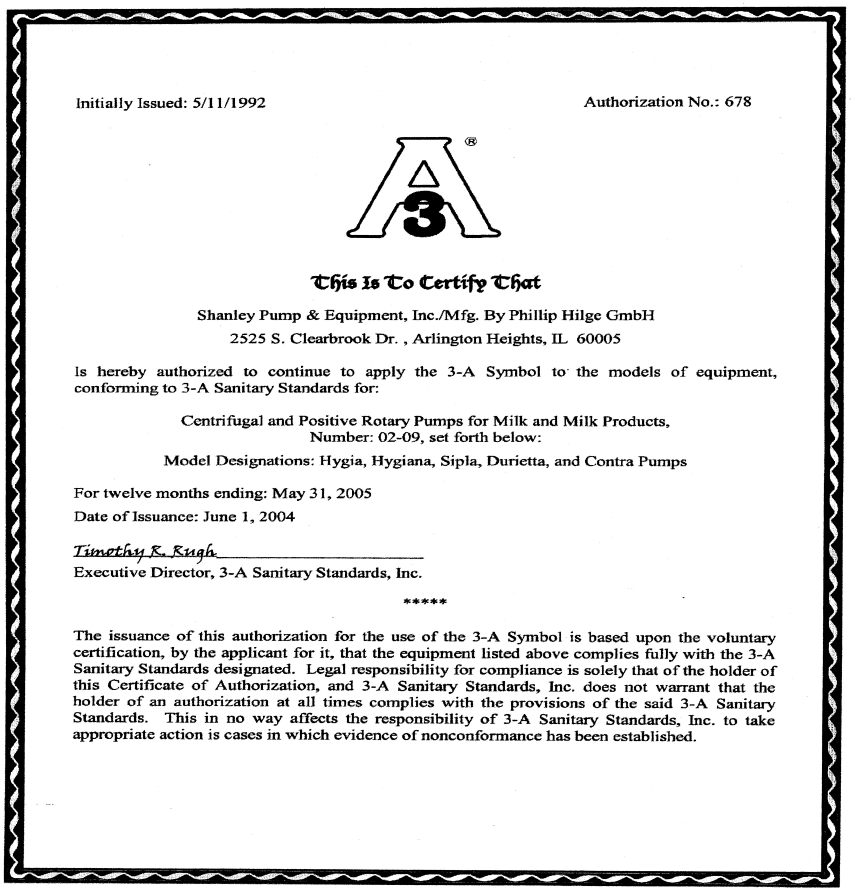
CERTIFICATE OF CONFORMITY

95-134

3A Certification

3A Certificate awarded by

the 3A Sanitary Standards Symbol Council



Initially Issued: 5/11/1992 Authorization No.: 678

This Is To Certify That

Shanley Pump & Equipment, Inc./Mfg. By Phillip Hilge GmbH
2525 S. Clearbrook Dr. , Arlington Heights, IL 60005

Is hereby authorized to continue to apply the 3-A Symbol to the models of equipment, conforming to 3-A Sanitary Standards for:

Centrifugal and Positive Rotary Pumps for Milk and Milk Products,
Number: 02-09, set forth below:

Model Designations: Hygia, Hygiana, Sipla, Durietta, and Contra Pumps

For twelve months ending: May 31, 2005

Date of Issuance: June 1, 2004

Timothy K. Rugh
Executive Director, 3-A Sanitary Standards, Inc.

*****

The issuance of this authorization for the use of the 3-A Symbol is based upon the voluntary certification, by the applicant for it, that the equipment listed above complies fully with the 3-A Sanitary Standards designated. Legal responsibility for compliance is solely that of the holder of this Certificate of Authorization, and 3-A Sanitary Standards, Inc. does not warrant that the holder of an authorization at all times complies with the provisions of the said 3-A Sanitary Standards. This in no way affects the responsibility of 3-A Sanitary Standards, Inc. to take appropriate action is cases in which evidence of nonconformance has been established.

Food and Drug Administration (FDA)

Relevant Regulations

Food and Drug Administration (FDA)

The FDA is a US Government agency which approves additives,food stuffs, cosmetics and pharmaceutical products for production and sale.

Only the the quality of the end product is regulated.

The process used its components, the materials of construction and design details of the production plant are also examined in order to make sure that they do not have a negative effect on the product being produced.

FDA approval is always related to the product.

There is no FDA approval for individual components.

- The manufacturing process and
- The technology used

are also assessed.

Legal Authorities

Standard	Validity	Law	Explanation
FDA	USA	Yes	The CFR are valid for all foodstuffs and pharmaceutical products sold in the USA, is also applied in other countries (South America, Asia)
3A-Standards	USA	Yes	
WHO-GMP	For all members of the WHO	No (see PharmBetrV)	
PIC-GMP	For all members of the PIC	No (see PharmBetrV)	Corresponds to EC-GMP
PharmBetrV	For all pharmaceutical companies in Germany	Yes	Translates WHO-GMP into German law
EC Machine Guidelines	For all members of the European Union	Yes	
DIN-Standards	Germany	No	When individual DIN Standards are indicated they are binding
VDMA-Standards	Germany	No	
Basle Standard	Primarily for the chemical industry in Basle	No	Guideline character

Good Manufacturing Practice

Good Manufacturing Practice (GMP)

The strong growth in the pharmaceutical production was the reason for the creation of rules and regulations governing correct production.

These rules and regulations are to be found in

Good Manufacturing Practice

The World Health Organisation (WHO) laid down the official GMP Regulations in 1968.

GMP lays down the standards for the industrial production of drugs.

The central statement of these regulations is that the quality of a product cannot solely be assured by the end control but is the sum of a row of provisions taken before, during and after production and packing of the individual product.

GMP Regulations

GMP-Regulations are:

- The revised WHO Basic Regulations for the Production of Drugs and the Assurance of their Quality (GMP)
- EC Guide to Good Manufacturing Processes, e.g. The Production of Sterile Drugs
- Basic Rules and Guidelines of the Pharmaceutical Inspection Convention (PIC)
- Internal Regulations of the the pharmaceutical companies
- EC-Machine Guidelines
  - –CE-Sign
  - –Rules and Regulations governing safety aspects
- DIN-Standards
- VDMA Standards
- other rules and regulations

The Material Difference

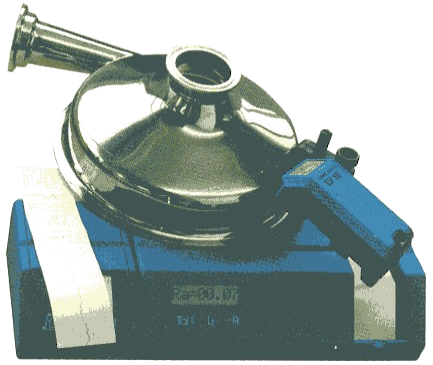
Pumps in heavy duty deep drawn and/or forged 316L stainless steel.

Smooth pore free surface finish for high degree of cleanability.

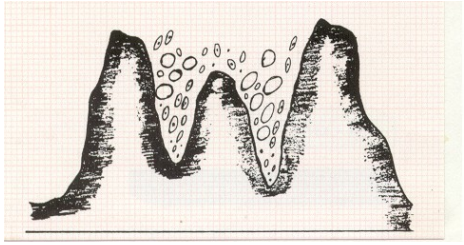
Electropolished and passivated surface finish to <0.4 µmRa.

FDA approved materials for pumps and seals.

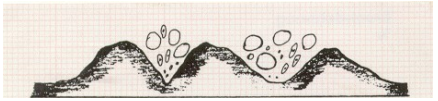
Material certification to EN10204.3.1b.



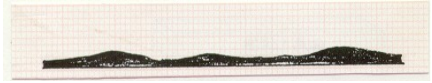
Surface Testing Machine



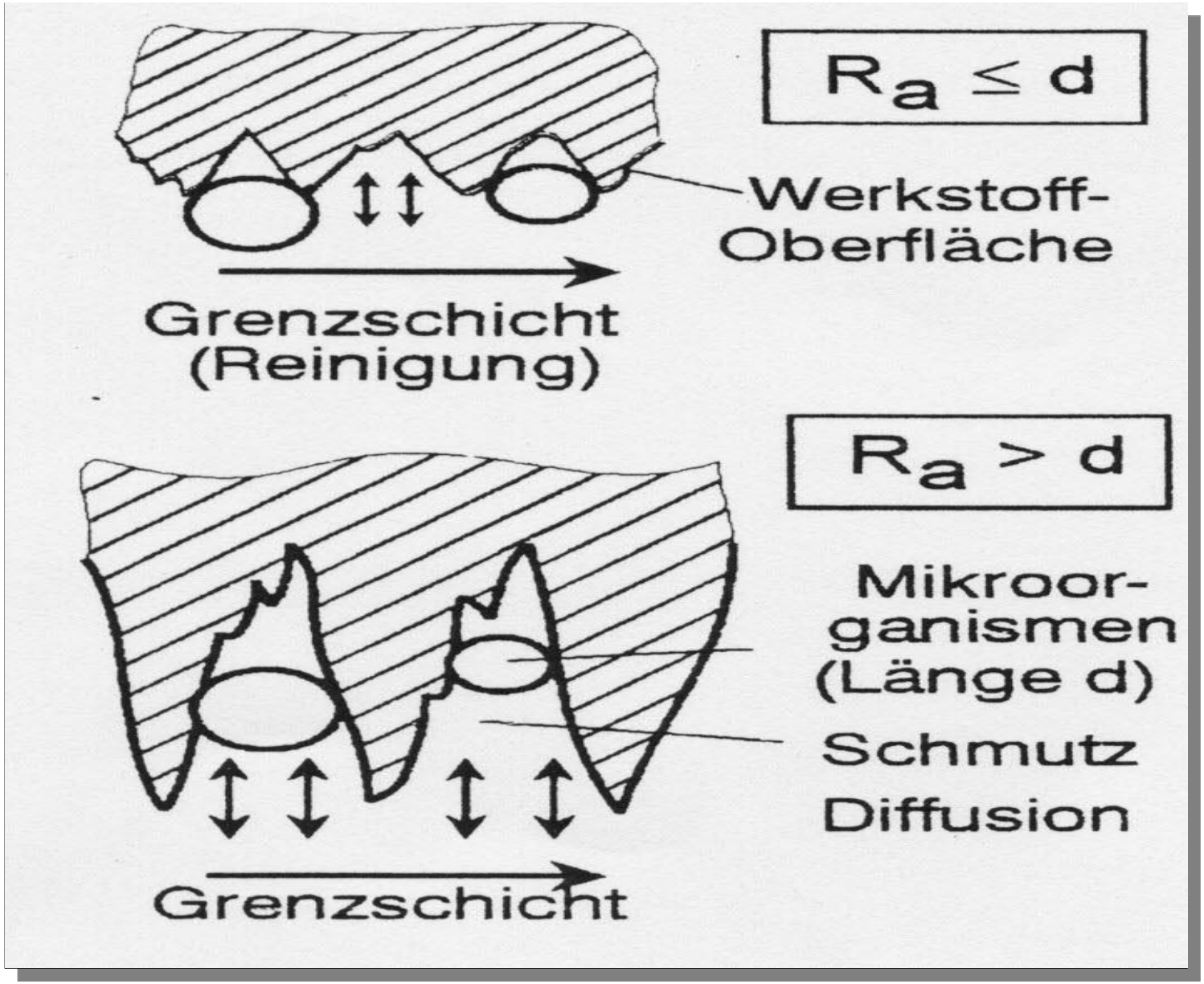
Sand Casting



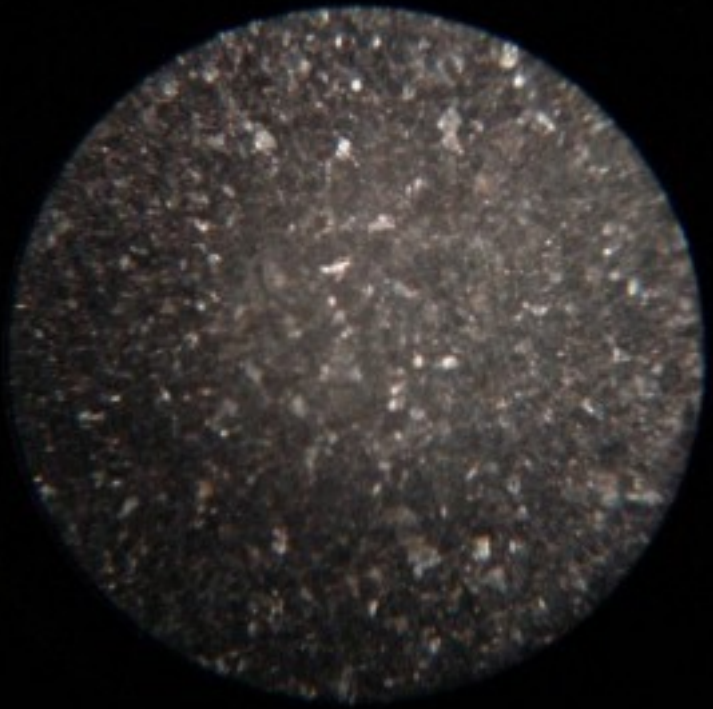
Precision Casting



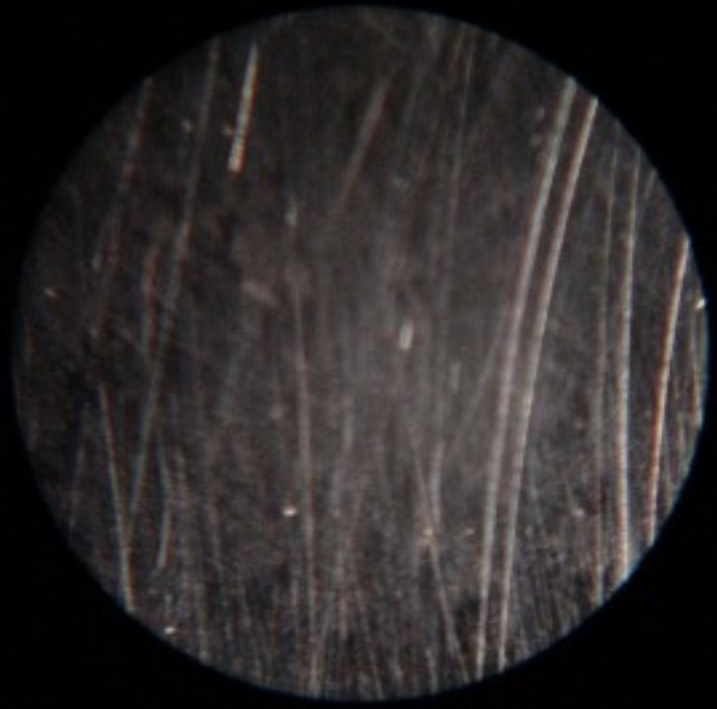
Rolled Steel


$R_a \leq d$
Werkstoff-
Oberfläche
Grenzschicht
(Reinigung)
$R_a > d$
Mikroor-
ganismen
(Länge d)
Schmutz
Diffusion
Grenzschicht

Kristalline Oberflächenstruktur



Kristalline Oberfläche
Oberfläche



Geschliffene

Fotos: Philipp Hilge GmbH & Co. KG

Sterile Standards

3A1 Hygienic Standard

Surface roughness ≤ 3,2 µm R_a

Option: Ferrite content ≤ 3%

CrNiMo-Rolled / Forged Stainless Steel to DIN (pore free low carbon quality)

1.4404 / 1.4435 (AISI 316L)

3A2 Sterile Standard

Surface roughness ≤ 0,8 µm R_a

Ferrite content ≤ 3%

CrNiMo

-Rolled / Forged Stainless Steel to DIN (pore free low carbon quality)

1.4404 / 1.4435 (AISI 316L)

Option: Ferrite content ≤ 1%, 1.4435 (AISI 316L)

3A3 Sterile Standard

Surface roughness ≤ 0,4 µm R_a

Ferrite content ≤ 1%

CrNiMo-

Rolled / Forged Stainless Steel to DIN (pore free low carbon quality)

1.4435 (AISI 316L)

All Elastomeres in contact with the liquid are FDA conform!

The Requirement Profile

These Regulations, Guidelines and Laws governing Sterile Pumps have a direct influence on the requirement profile with regard to...

... The choice of materials

... The quality of the surface finish

... The design features of the wet end parts

... The documentation for the materials used

Basic Requirements for Wet End parts

- Apparatus and components (pumps) must be fitted with a drain.
- Corners and edges must be rounded off.
- Dead ends should be avoided, paying attention to the relationship of l/d.
- Connections and seal areas must be crevice free.
  (Example DIN 11864 to DIN 11851)
- Gaps, surface faults (cracks and scratches) must be avoided.
- Embossing and socket head screws should not be used.
- Sterile seals should be encapsulated and totally flushable.
- Casing seals should have a metallic contact which ensures a defined pressure on the seal.

Summary of the Requirements:

Non Toxic, tasteless and corrosion resistant materials with a smooth surface which is easy to clean.

Aim:

To avoid design weak points which would favour the depositing of pollulants and the growth of bacteria.

Result:

Assured cleaning with less effort.

Regulations, Guidelines and Laws governing Hygienic Pumps

3A - Standard

FDA
ASME BPE-2002

GMP

Every single guideline effects the requirement profile of the pump!

EC - Machine Guidelines

DIN
e.g. DIN EN 12462

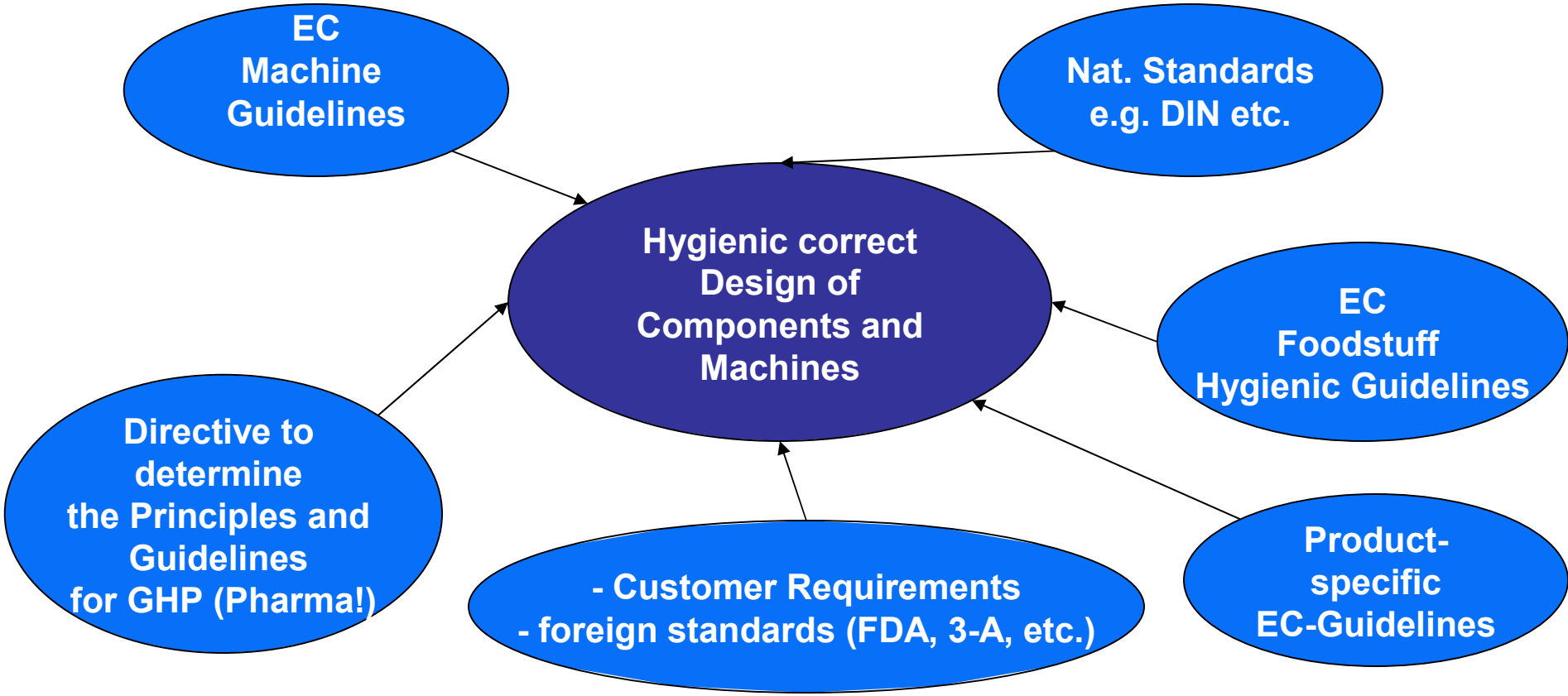
Customer Standards

- AVENTIS
- BAYER
- FRESENIUS
- ...

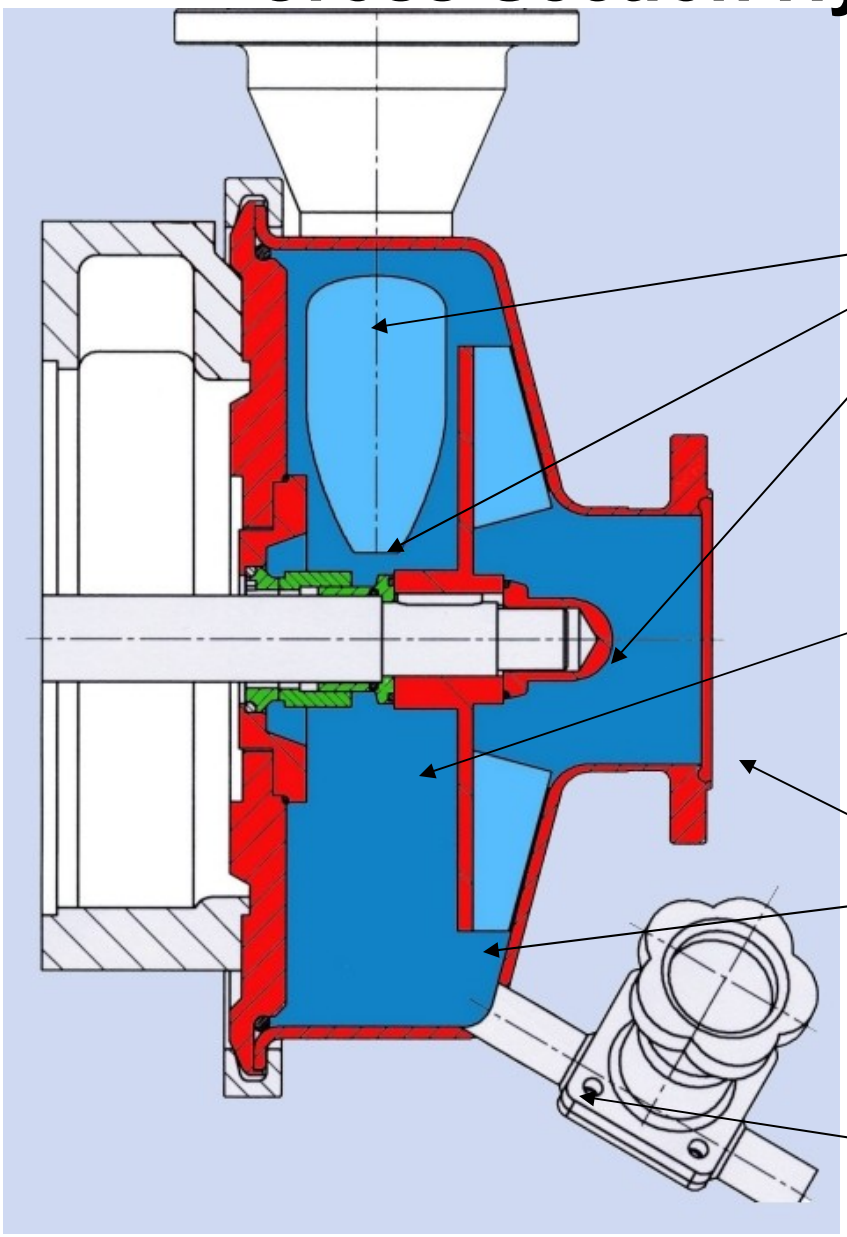
Qualified Hygienic Design

The hygienic correct design of components and machines is stipulated by numberless rules and regulations. It is becoming more and more difficult to keep a track of all of them.

VDMA and the Machine/Apparatus Faculty of the University of Weihenstephan have summarised all the regulations and guidelines in a checklist.



Cross Section Hygienic Design



Gap Free Seal Areas

Single Mechanical Seal

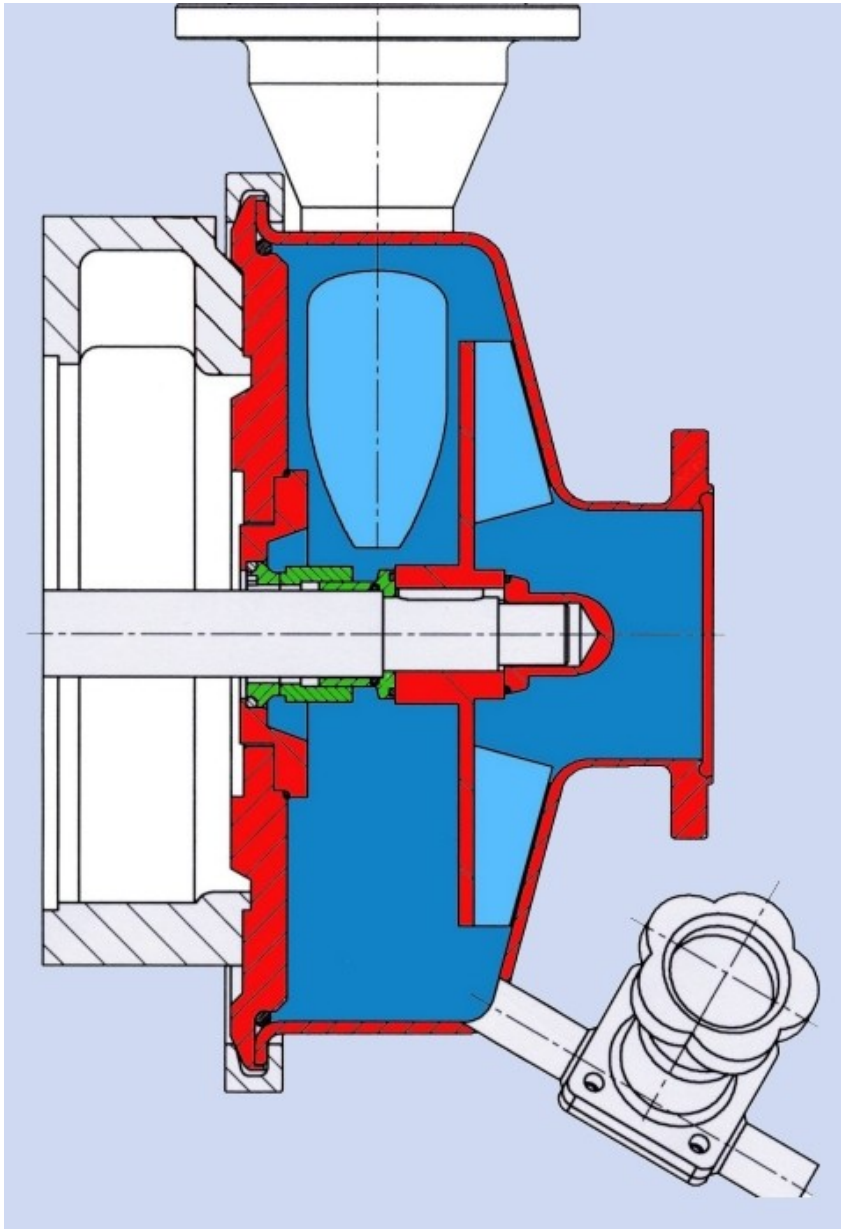
Option:

Double Sterile Seal in Tandem Design, lost flush

Dead End Free Pump Casing

Optional Casing Drain at lowest Point

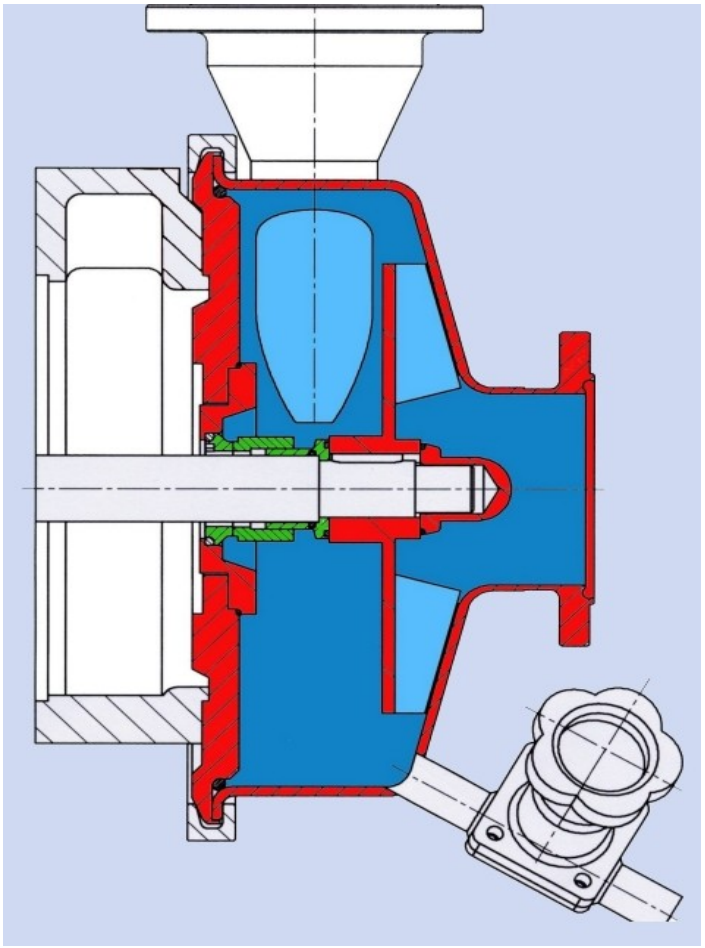
Cross Section of Sterile Design to EHEDG

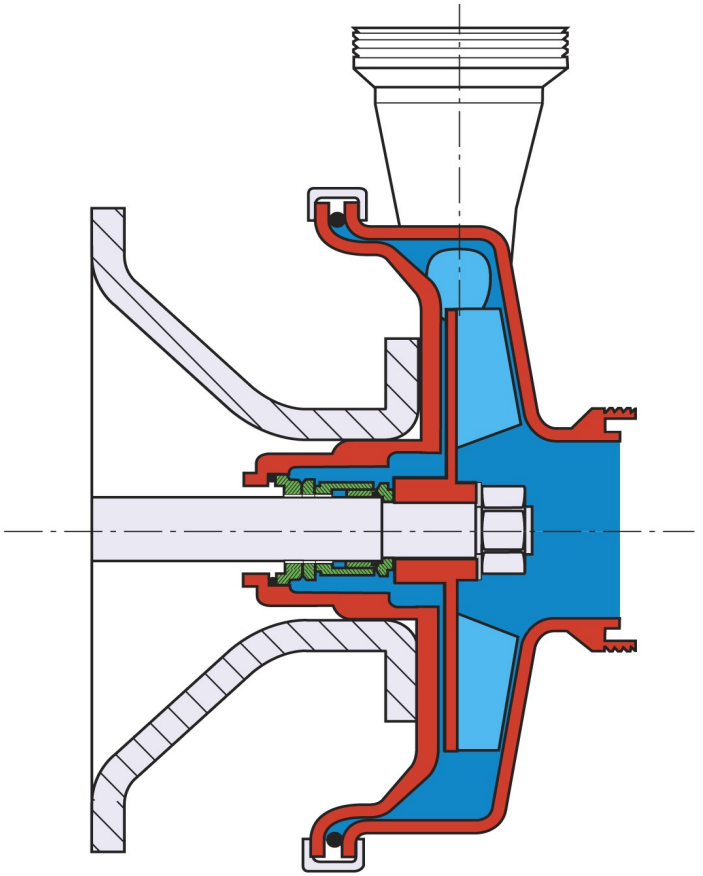


The cleanability of the sterile pumps
has been tested and approved according to the regulations of the European Hygienic Engineering & Design Group (EHEDG).

These tests are the warranty for the safety of carrying out sterile processes!

Cross Section different brands





Flexibility

Choice of impellers:

channel.

closed

free flow

(semi-)open

Flexibility

Choice of connection size and type including:

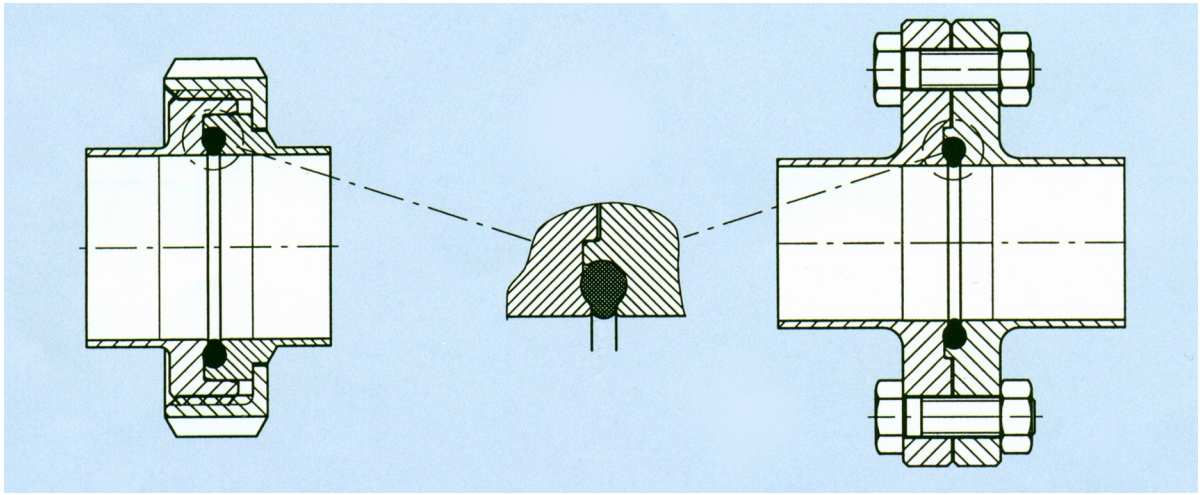
Threaded: DIN 11851, DIN 11864-1, RJT, IDF, SMS etc.

Flanged: DIN 2633, BS, ANSI, DIN 11864-2 etc.

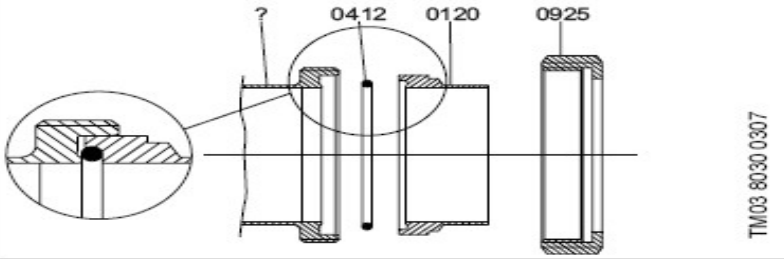
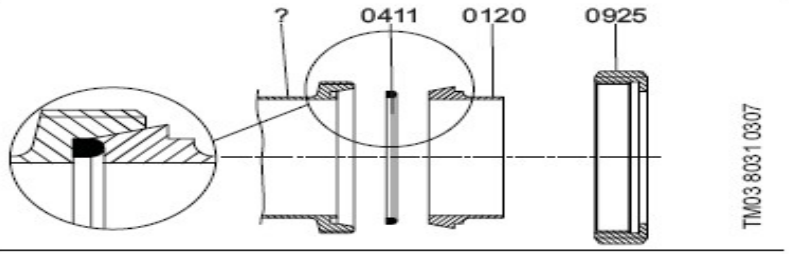
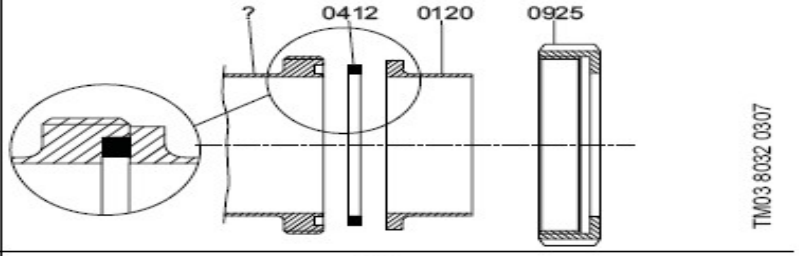
Clamps, Tri-Clamp, DIN, ISO.

Other special threaded, flanged, clamp connections on request.

Discharge branch positionable through 360^{o} on most pump models.



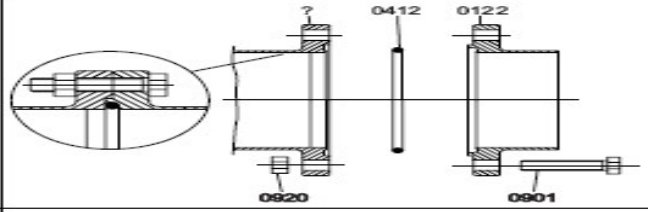
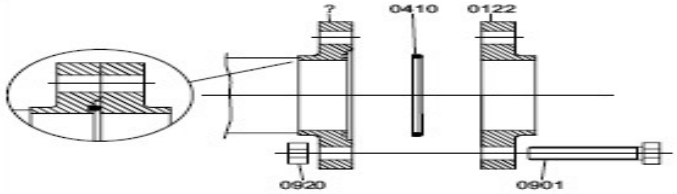
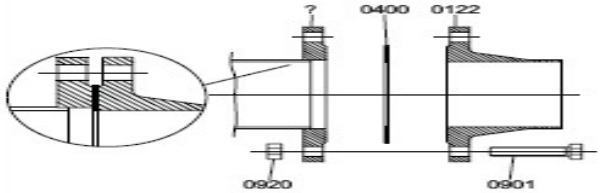
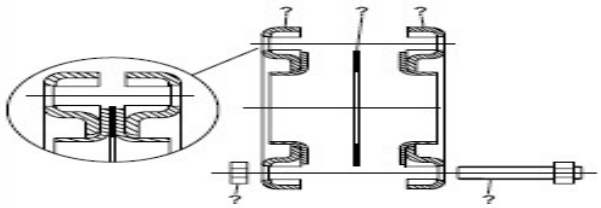
Threads

Connection	Standard	Construction
Aseptic threaded connection Typical applications: • • • • •	DIN 11864-1	
Threaded connection Typical applications: • • • • • •	DIN 11851	
Threaded connection, SMS Typical applications: • • • • •	??	
Threaded connection (male)	ISO 228	??
Threaded connection, GAZ (male)	DIN ISO 228 GAZ	??
Threaded connection (female)	DIN 2999	??
Threaded connection, APV-FG1	DIN ISO 228	??
Threaded connection, BSP	??	??
Threaded connection, RJT	??	??

Description of components

Pos.	Description	Material
??	Threaded connection in pump housing	
0120	Threaded connection	
0411	Circular joint ring	
0412	O-ring	
0925	Grooved union nut	

Flanges

Connection	Standard	Construction
Aseptic flange Typical applications: - - - -	DIN 11864-2	
Flange Typical applications: - - - -	APV FN1/FG1	
Flange	DIN EN 1092-1 (DIN 2632)	??
Flange, fixed flange Typical applications: - - - -	DIN EN 1092-1 (DIN 2633)	
Flange	DIN EN 1092-1 (DIN 2633/2642)	??
Flange, loose flange Typical applications: - - - -	DIN EN 1092-1 (DIN 2642)	
Weld neck flange	DIN EN 1092-1 (DIN 2633)	??
Kremo-flange	DIN EN 1092-1 (DIN 2633)	??
Flange, APV FN1/FG1	??	??
Flange, APV	??	??
Flange	ANSI 150 and 300 LB RF	??

Description of components

Pos.	Description	Material
??	Flanged connection in pump housing	
0122	Flanged connection	
0400	Gasket	
0410	??	
0412	O-ring	
0901	Hexagon screw	
0920	Hexagon nut	

Flexibility

Choice of mechanical seal materials. Single internal, double tandem or back to back. External seals available as option.

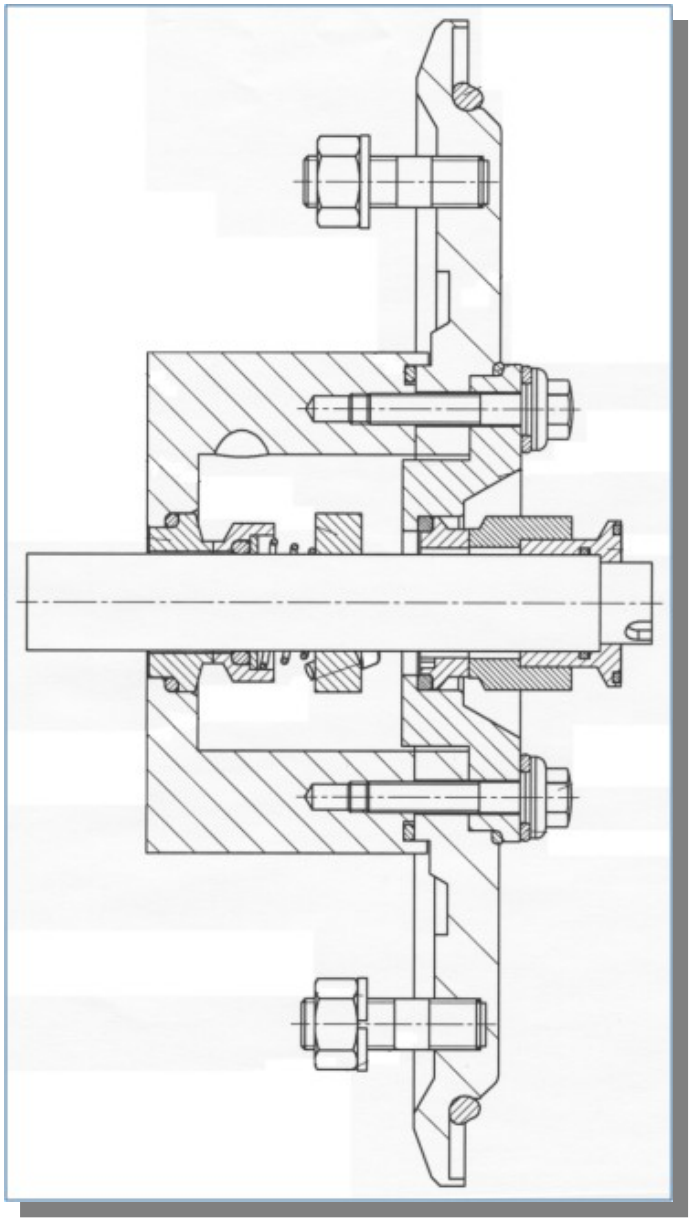
Single mechanical seal

Sterile mechanical seal

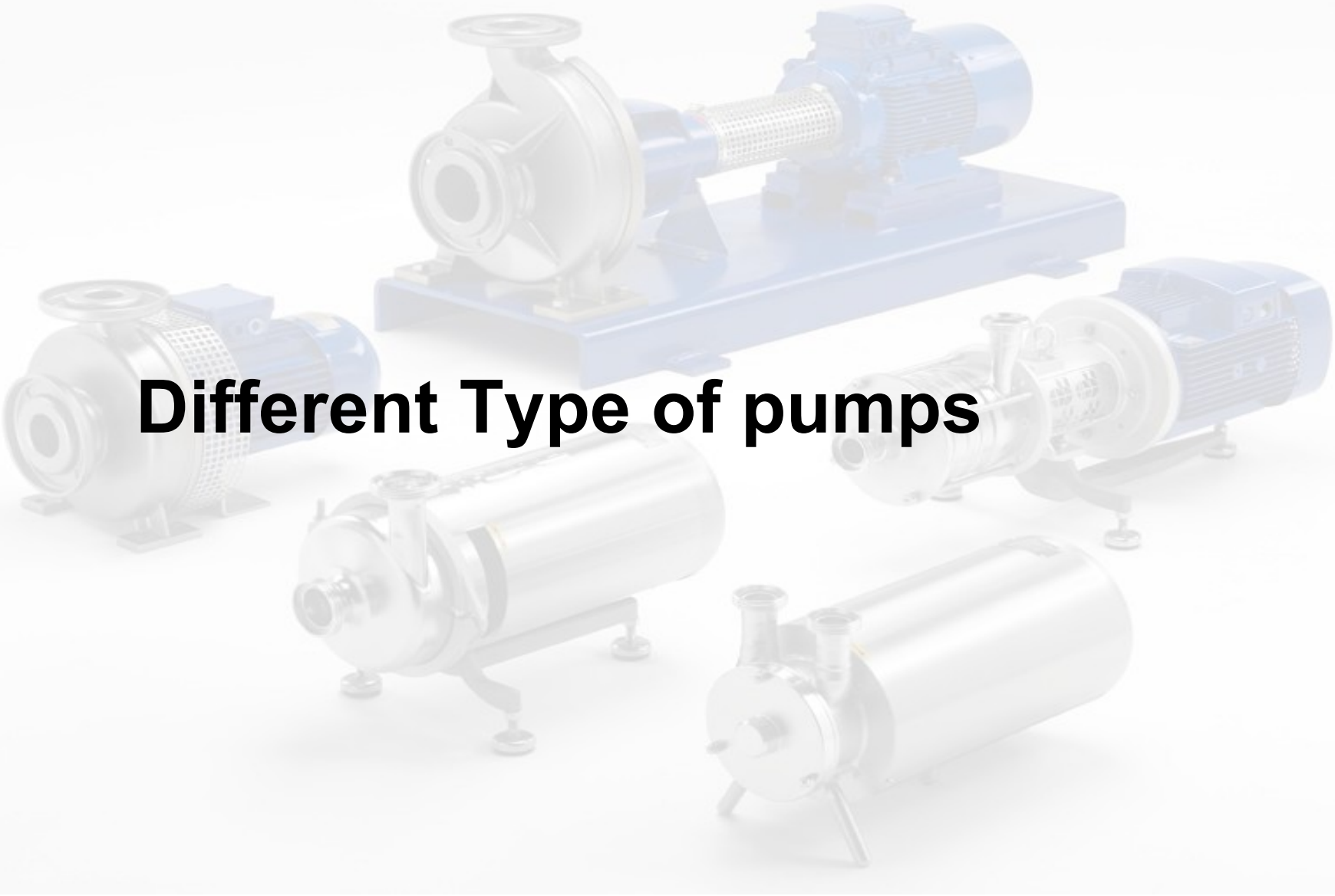
Choice of motor type and manufacturer

Dubbel mecanical seal

Atmosphere



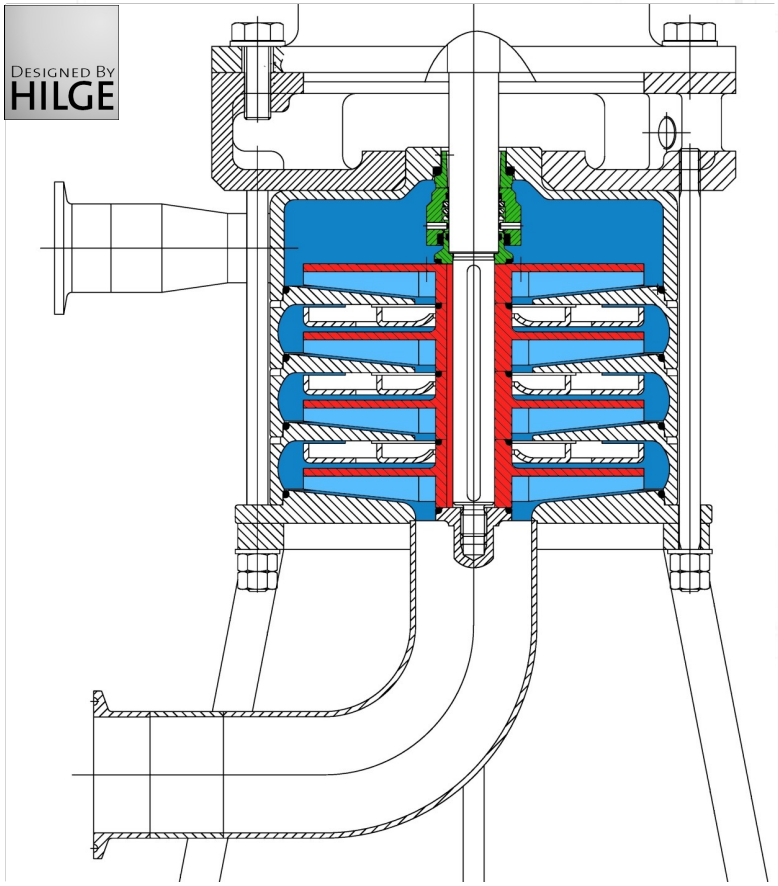
Produktseite



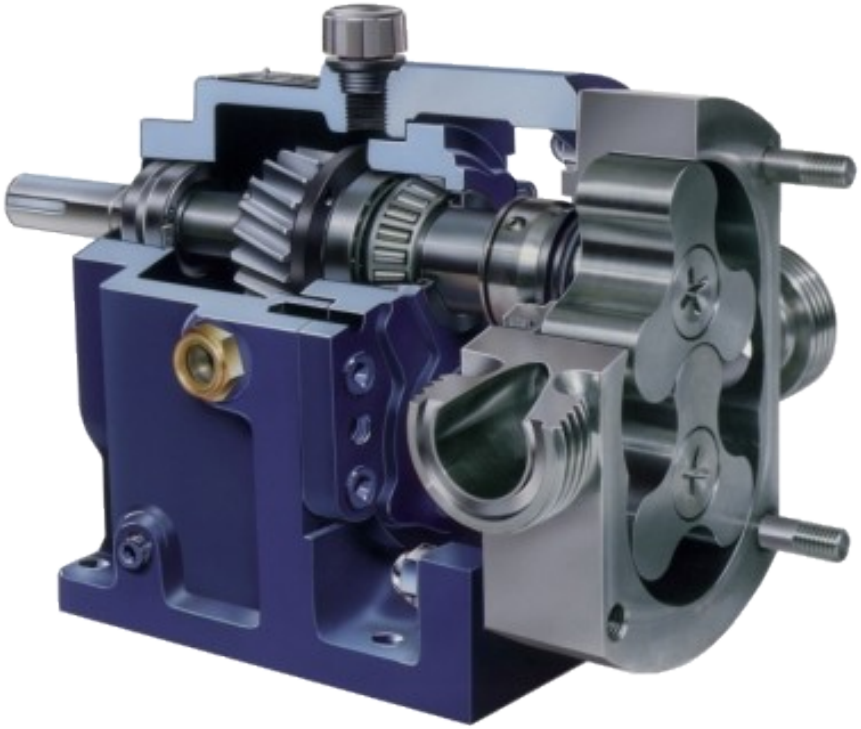
Different Type of pumps

Unique Hygienic Design

Also multistage



Rotary Lobe Pump

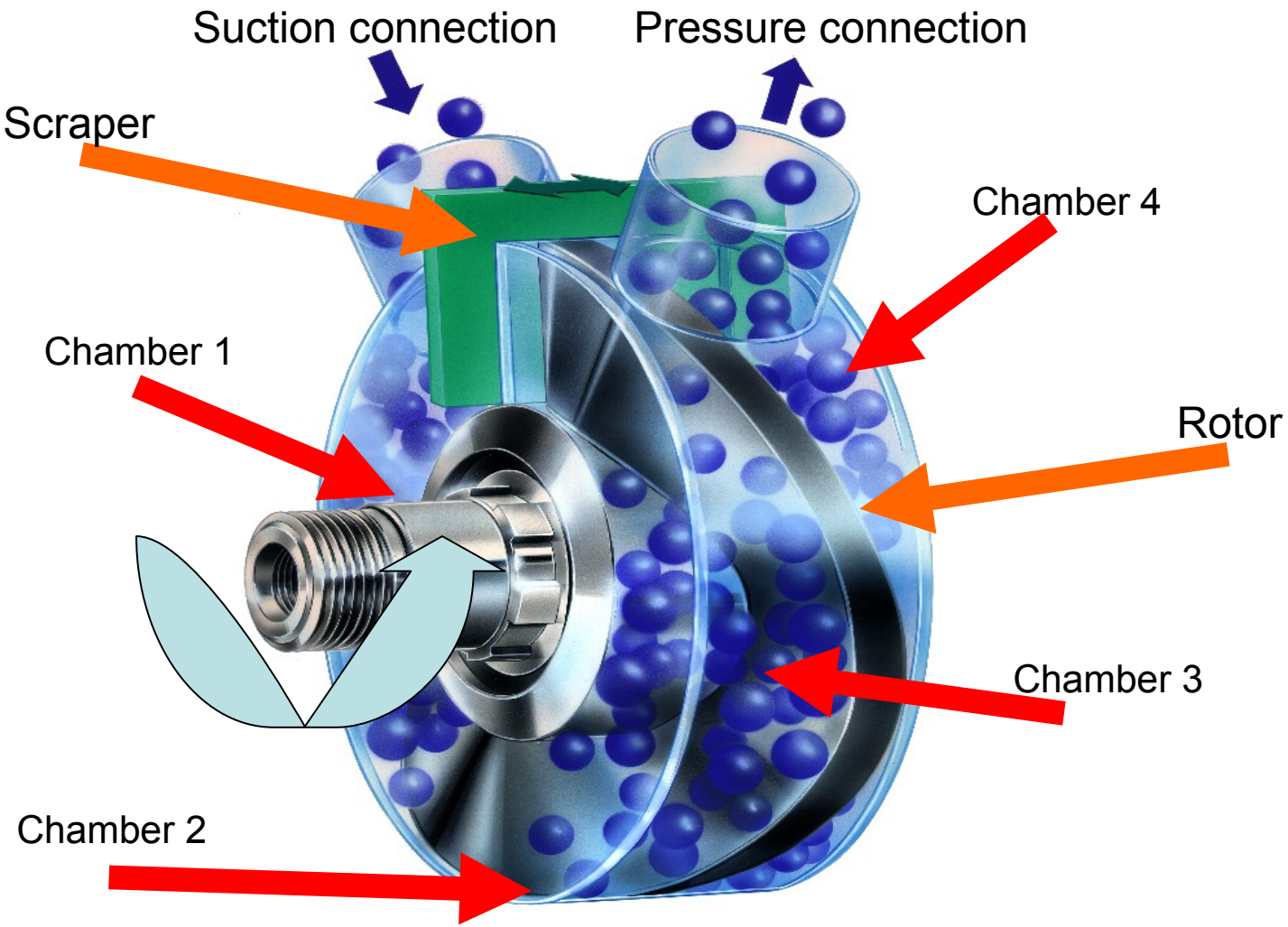


For highly viscous fluids.

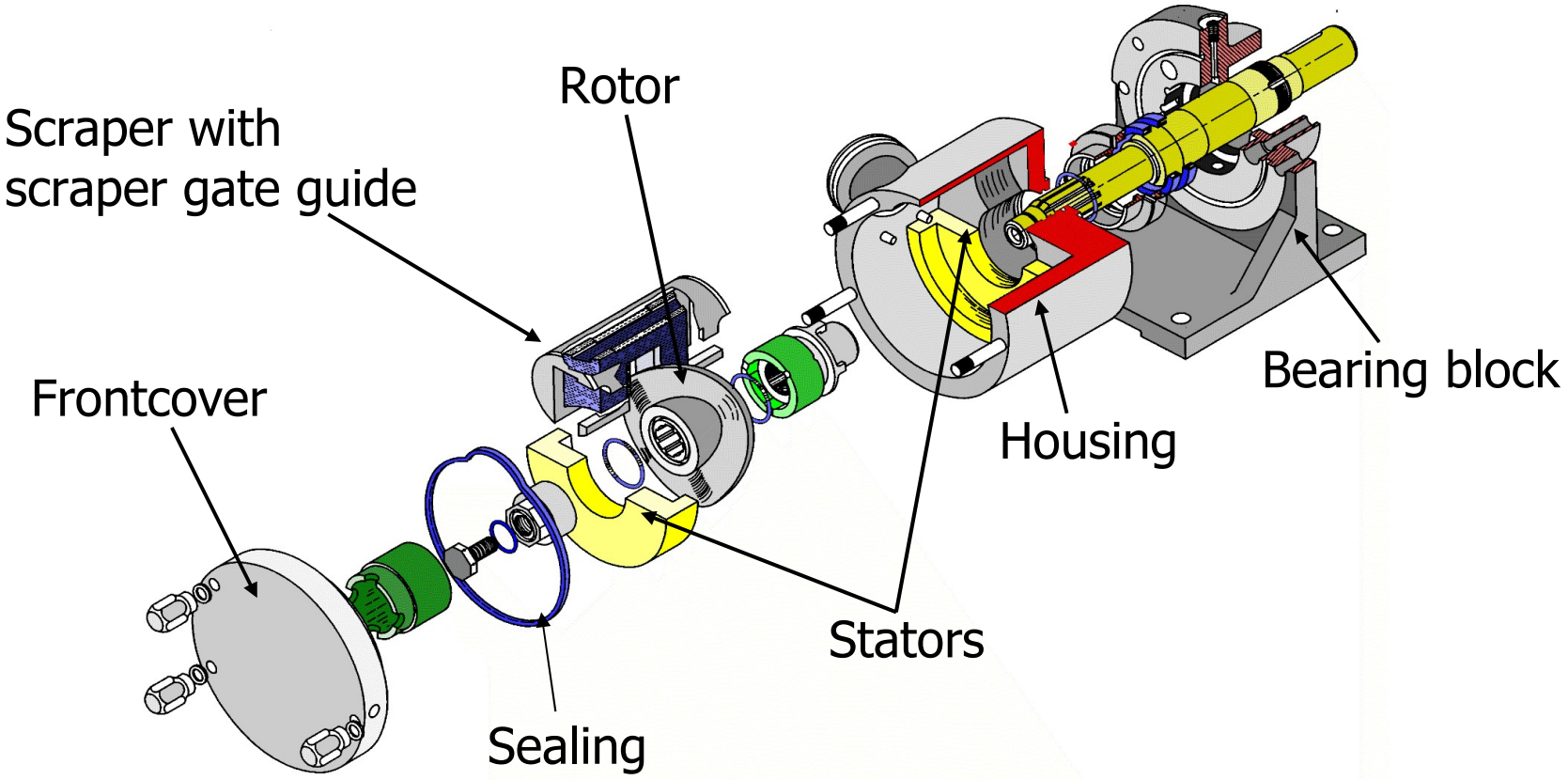
- Tri-lobe rotors for smooth flow and gentle product handling.
- Hygienic design suitable for CIP and SIP.

The SINE Pump – Type SPS

The SINE – Principle



Components Sine -pump



SANITARY Diaphragm Pumps

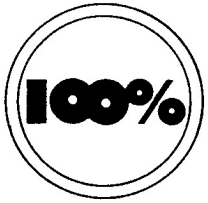
CLEAN IS THE KEY

CERTIFIED EHEDG HYGIENIC ENGINEERING & DESIGN THROUGHOUT EUROPEAN

TYPE EL
MARCH 2002

Why are Air Operated Diaphragm pumps so popular?

1. Advantages of Air Operation



On-Demand Performance and 100% Energy Efficiency

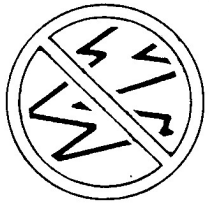
When you close the fluid outlet of a Diaphragm Pump, the pump stops. No movement, no wear, no overload, no heat build-up and no power consumption - 100% energy efficient.

Pollution-Free Operation - No Exhaust Fumes

Diaphragm Pumps exhaust clean, slightly-chilled air, not potentially dangerous carbon monoxide.

Cannot Overheat

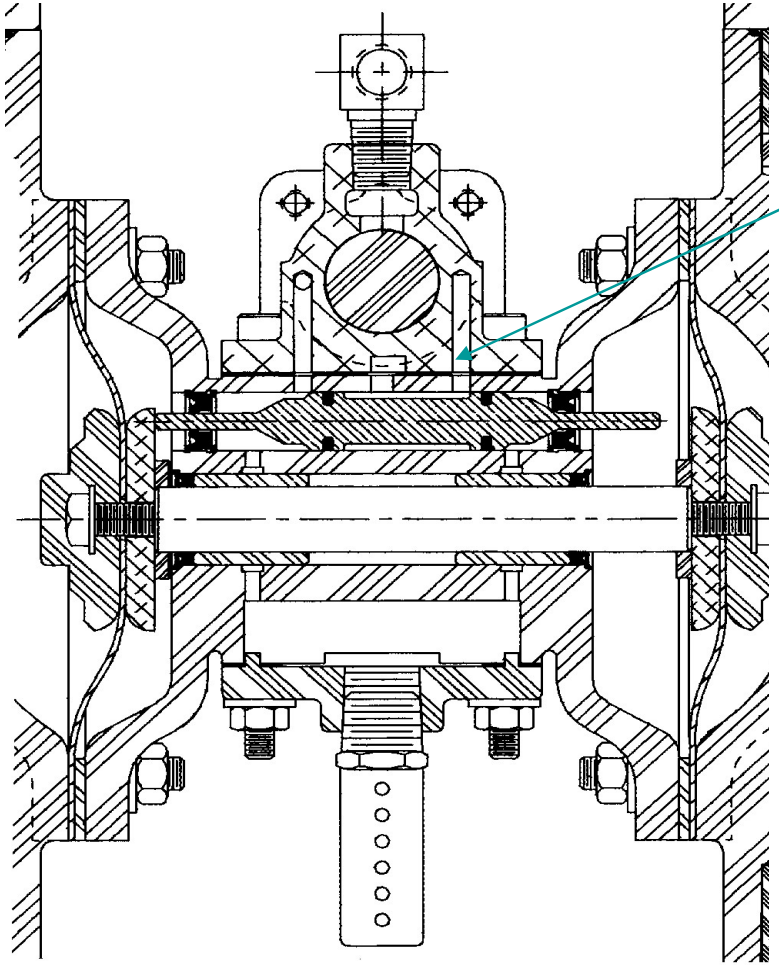
Since there are no heat-generating electrical components, Diaphragm Pumps stay cooler. If you are pumping solvent-based fluids, this means reduced solvent flash-off.



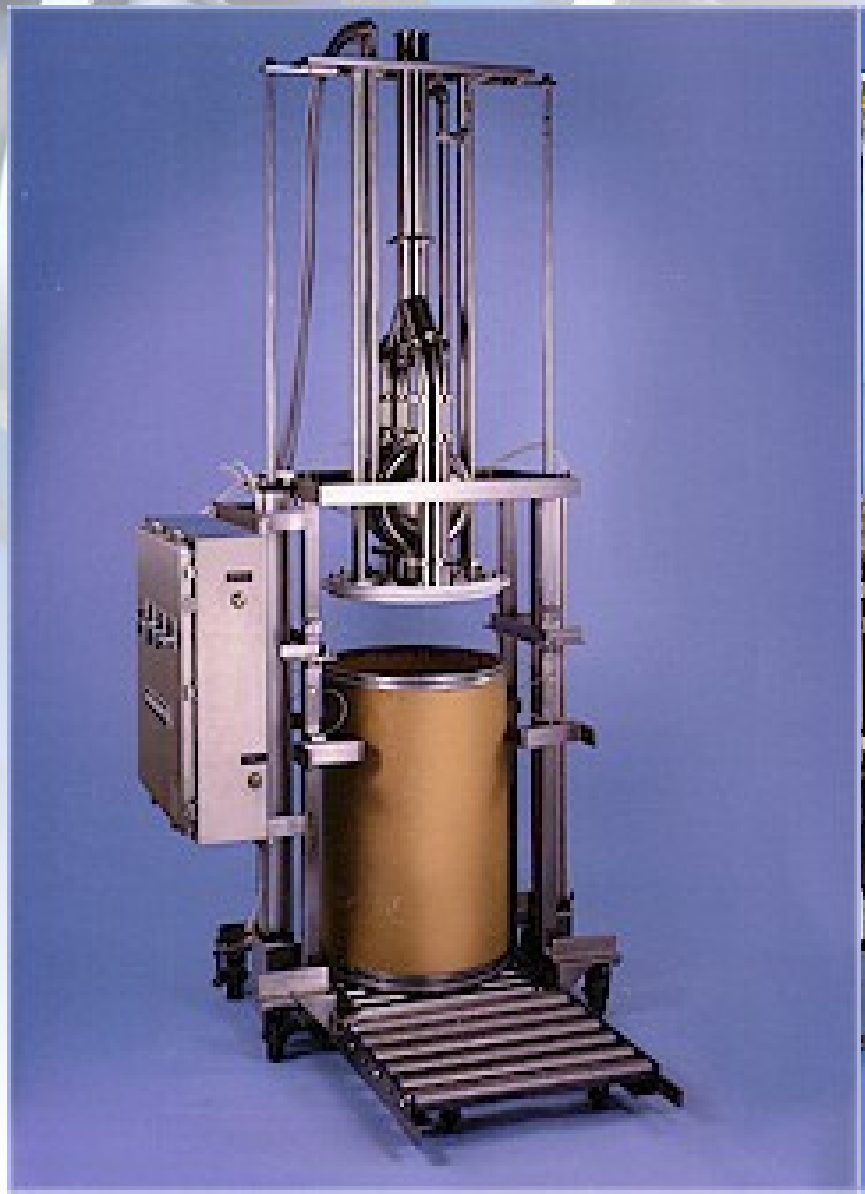
No Electrical Spark

Since Diaphragm Pumps operate on compressed air, there is no danger of an electrical spark or any need for expensive explosion-proof motors or enclosures.

Principles of Operation



Continuous high pressure signal to the main spool



Terms to be remembered

CIP:

Cleaning **i**n **P**lace = automated cleaning cycles that are used to clean complete systems, production lines or units. There are national standards in some countries such as DIN 11 843 in Germany that lay out the procedures and cleaning agents to be used.

SIP:

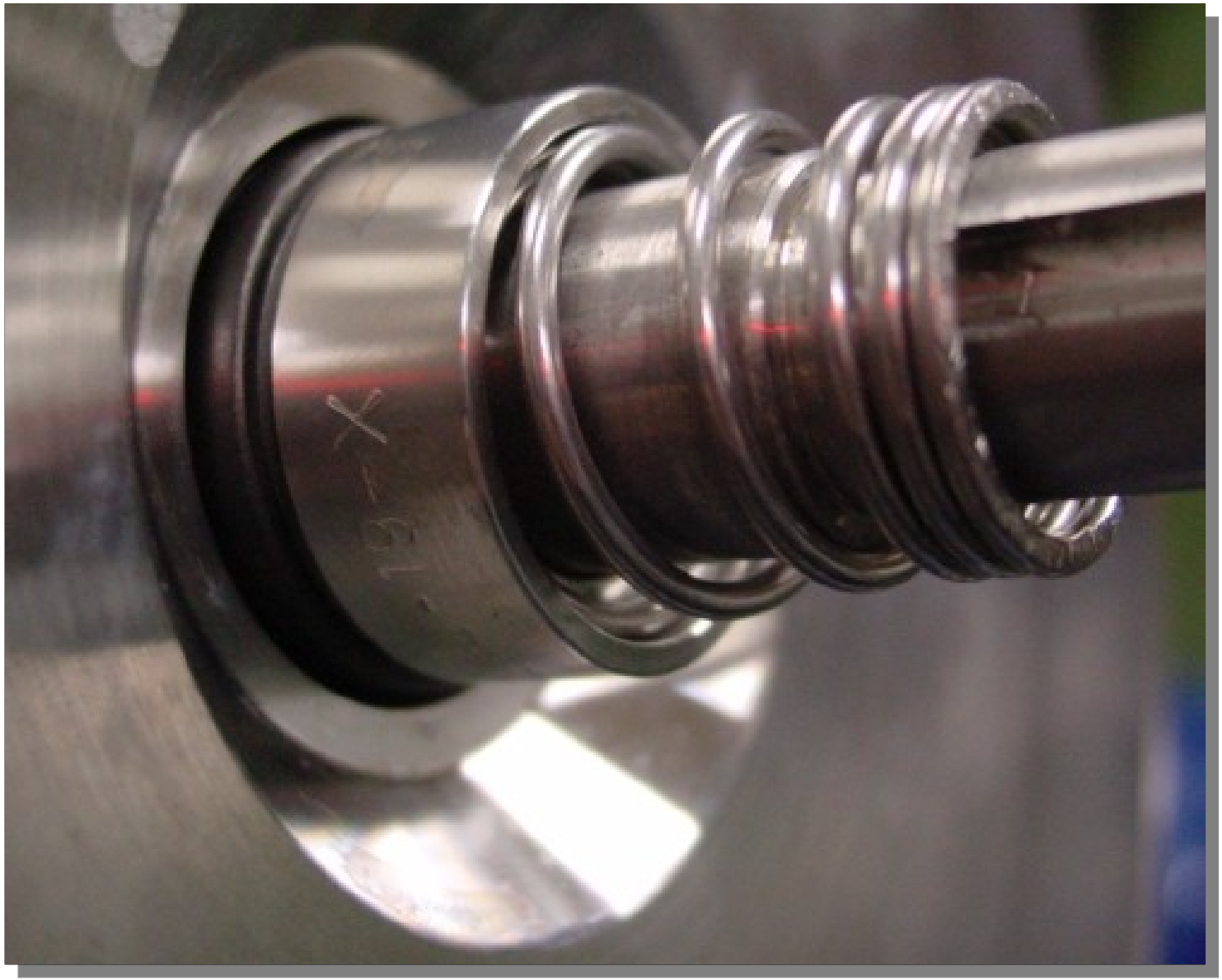
Sterilisation **i**n **P**lace = is employed in some processes, especially in pharmaceutical and bio-processing applications.

After CIP the system is flooded with steam at temperatures between 120°C and 130°C. The pumps are standing still during this operation.

Sanitizing:

Sanitizing is a process employed in the pharmaceutical industry on WFI applications instead of SIP. WFI is gradually heated up to about 125°C and circulated through the loop for a certain period of time. The pumps are operating all the time and above the critical temperature of 80°C the mechanical seals are poorly lubricated – **pay attention to mechanical seal selection**.

Negativbeispiel Federdichtung



Ungünstiger Einbau


Thank you for your Attention
Questions?