

GEMÜ P40

Pneumatically operated tank bottom valve

EN

Validation Guide



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further information
webcode: GW-P40



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1 Introduction to the Validation Guide

This Validation Guide documents the test sequence carried out on the product for the purposes of product release. The implemented test sequence includes mechanical stress and performance tests carried out on the individual components. Tests were also carried out on extractables, the purity (particle content) of media-wetted components and the biological safety of the product.

The information contained in this document was checked for correctness and completeness at the time of publication in February 2026. The product data may change without prior notice.

In case of doubt or misunderstandings, the German version is the authoritative document. Please contact your local GEMÜ sales partner or GEMÜ directly for up-to-date information.

2 Product description

The pneumatically operated GEMÜ P40 PD tank bottom valve is designed for use in sterile applications. The sealing concept of the valve is based on the GEMÜ PD technology comprising a radial sealing PTFE diaphragm, whereby the actuator is hermetically separated from the medium. All actuator parts (except the seals and design elements) are made from stainless steel. It is available with a "Normally closed" control function (further control functions possible on request). The valve has an optical position indicator with a transparent cap as standard.

3 Product features

- Low-maintenance due to PD sealing technology, so no retightening is required
- PD design with optimized draining and compact valve body design
- Converging design of the tank-side area to avoid potential sediment deposits
- Suitable for use in hygienic and aseptic applications (CIP/SIP capable and autoclavable)
- Fast, safe and simple actuator mounting
- Optical position indicator and transparent cap as standard
- Simple modular expansion possible due to state-of-the-art automation components
- Suitable for vacuum up to 70 mbar (a) as standard

4 Technical specifications

- Media temperature: -20 to 160 °C
- Ambient temperature: -20 to 80 °C
- Operating pressure: 0 to 6 bar
- Nominal sizes: DN 6 to 65
- Body configurations: Tank bottom valve body
- Connection types: Clamp | Pipe bend | Spigot
- Connection standards: ASME | DIN | EN | ISO | SMS
- Body materials: 1.4435 (316L), block material | 1.4539 (904L), block material
- Seat seal materials: PTFE

Technical data dependent on the respective configuration

5 Test sequence carried out

The PD tank bottom valve GEMÜ P40 meets the following test conditions:

Approval-relevant examinations/endurance tests	Test results			
	G_R015	J_R025	M_R040	P_R050
Sterile endurance test (GEMÜ 2, see Appendix)	> 250 cycles	> 250 cycles	> 200 cycles	> 125 cycles
Change in climate -10/+60 °C (Timing cycle (f): G & J: 2/2, M & P: 4/4)	> 100,000 CD	> 100,000 CD	> 100,000 CD	> 100,000 CD
Hot oil 160 °C/p _s = 6 bar(g)	> 100,000 CD	> 75,000 CD	> 50,000 CD	> 50,000 CD
Leak test in accordance with EN 12266-1 Leakage rate A (P11/P12)	Confirmed			

Additional tests carried out	
Vacuum compatibility p _s = 0.016 mbar (a)	Can be confirmed up to 0.05 mbar (a)
Low temperature down to -40 °C	Seat leak tightness can be confirmed up to an operating pressure of 6 bar(g) at temperatures down to -20 °C. Below -20 °C, seat leak tightness may be limited depending on cycle duties and operating pressure.
Validation of the welding-in specifications in accordance with the operating instructions, followed by a leak test (6 bar x 1.1)	Confirmed
Fluorescence test with riboflavin based on VDMA leaflet	No penetration of liquid into the sealing area of the PD

Material resistance/cleaning media			
Test medium	Concentration (%)	Contact duration (hrs)	Temperature (°C)
ECOLAB P3	5	168	40
Asiral SRC-A	4	168	RT
Deptil PA15 Plus	5	168	40
Diversey Acidplus VA35	2	168	80

Simulations	
Structure/strength simulation of the seal (PD)	The geometric design of the PDs is based on an FEM calculation. The geometric optimum is determined iteratively.
Structure/strength simulation of the valve body	Simulative analysis of valve bodies; no burst tests required
Cleaning simulation based on the EHEDG test	Good cleanability/prerequisite for obtaining the EHEDG certificate

Conformities	
Machinery Directive 2006/42/EC	Risk evaluation carried out and documented
Pressure Equipment Directive 2014/68/EU	Hazard and risk analysis carried out and documented
Foodstuff conformities Regulation (EC) No. 1935/2004 and 10/2011	Confirmed by an external laboratory
USP Class VI <87> and <88>	Confirmed by an external laboratory
FDA 21 CFR 177.1550	Confirmed by an external laboratory
GB 4806.7-2023	Confirmed by an external laboratory
Japanese Food Contact Material Act	Confirmed by an external laboratory
FMEA	D-FMEA and P-FMEA carried out and documented

- f = timing cycle in seconds, e.g. 5/5 = 5 seconds closed/5 seconds open
- CD = cycle duties

6 Appendix

GEMÜ 2			
Test step	f [s]	CD	t [s]
Stabilization of steam		1	
Application of steam	5/5	90	900
Application of vacuum		1	60
Ultra pure water stabilization			
Application of ultra pure water	5/5	90	900
Application of vacuum	5/5	45	450
Total cycle		227	2310



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Subject to alteration

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