

Certificate of Compliance to ASME BPE

Endress+Hauser GmbH+Co. KG certifies that the instrument furnished with this shipment is in compliance with the model numbers requested on the referenced purchase order and published Endress+Hauser specification. The instrument provided was manufactured, tested and inspected in accordance with accepted industry manufacturing practices, and Endress+Hauser procedures.

Sales Order Number:

Customer Name:

Customer PO Number:

Surface Finish:

Delta Ferrite:

Order Code:

Serial Number:

Tag Number:

[REDACTED]
[REDACTED]
[REDACTED]
Ra \leq 0.38 μ m / 15 μ inch, electropolished
<1%
[REDACTED]
[REDACTED]

Date: 25.04.2015

Endress+Hauser GmbH+Co. KG

D-79689 Maulburg

i. A. Ilona Buschbaum

Inspector

This document was generated electronically and is valid without signature.

ASME BPE-2012 General Requirements

Endress+Hauser holds an ISO9001 certificate. Our quality assurance program describes the systems, methods, and procedures used to control materials, drawings, specifications, fabrication, assembly techniques and examination/inspection used in the manufacturing of the instrument, as per GR-3.

Endress+Hauser allows free access to the area of assembly, fabrication, welding and testing of owner/user and authorized inspection personnel at all times while of work on instruments is being performed, as per GR-4.4.

The Liquiphant is delivered with a comprehensive set of documentation according to GR-5.1.1. Additional drawings, approvals, Certificate of Compliance (CoC) and testing and examination documentation will be supplied, if requested.

Verifications of Material Test Reports (MTRs) are examined for all metallic process components that come in contact with the product, as per GR-5.2.1.

With the unique serial number of the instrument the date of assembly and welding can be identified. Each welder is registered in the ERP system. Welding is performed and examined according the particular weld map as per GR-5.3.4. Welder and welding operator performance qualifications are in accordance to ISO9606 / ISO14732.

A Certificate of Compliance in regards to the electropolishing and related passivation processes is provided if applicable and requested, as per GR-5.4.1.

This CoC certifies the compliance of the seal exposed to process contact fluids to the FDA and United States Pharmacopeia (USP) directive with regards to USP <87> and USP <88> Class VI on biological reactivity if applicable (compound of O-ring delivered with selected process connection or static seal delivered with selected weld-in adapter specified in Technical Information TI), as per GR-5.6.

All documentation is accessible online via the Common Equipment Record of Endress+Hauser.

The Liquiphant is designed, developed and produced based on the applicable referenced standards of the GR-7.

ASME BPE-2012 System Design

The Liquiphant is designed for biopharmaceutical equipment, as per SD-2.

The Liquiphant does withstand continuous flow of saturated steam at a minimum temperature of 266°F (130°C) for duration of 100hrs minimum under continuous steady-state conditions, as per SD-2.3.1.1.

Fabrication of the Liquiphant is performed in facilities where the product contact surfaces are protected from contamination. The Liquiphant is cleaned with a suitable cleaning agent and covered for protection before shipment. No preservative fluid is used after that cleaning, as per SD-2.4.

In addition no material of animal origin is used in components that came in contact to the process, and during the manufacturing, assembling, and polishing processes.

The Liquiphant wetted parts are constructed of 316L (ASTM / UNS S31603 / EN/DIN 1.4435) stainless steel according to SD-2.4.1. Nonmetallic material (O-ring or static seal of selected weld-in adapter) are in conformance to FDA 21CFR177 and USP Class VI. The welding for process surfaces has been qualified for low delta ferrite content. The delta ferrite content is indicated on page 1 of this CoC.

All surfaces are cleanable. All surface imperfections have been eliminated, as per SD-2.4.2 (a). Internal horizontal product contact surfaces are minimized, as per SD-2.4.2 (b). The Liquiphant is drainable and free of areas where liquids may be retained and where soil or contaminants could collect, as per SD-2.4.2 (c). All product contact surfaces are accessible to the cleaning solutions and are accessible to establish and determine efficacy of the cleaning protocol, as per SD-2.4.2 (d). Fasteners or threads are not exposed to the process and no engraving or embossing of materials (for identification or traceability reasons) has been made on the process contact side, as per SD-2.4.2 (e), (f). Internal angles <135 deg and radii < 1/8 in. (3.2 mm) do exist due to functional reasons, however the product contact surfaces are readily accessible for cleaning and examination, as per SD-2.4.2 (g).

The owner/user may agree on the use of the process connection "Ingold" although not fulfilling all requirements of the 3-A sanitary standard.

The Liquiphant is constructed out of corrosion resistant material which withstands wash-down and harsh cleaning solutions according. The exterior design of the non-product contact surfaces conforms to the following SD-2.4.4.2 (a), (c), (d), (l).

The owner/user may agree on the use of aluminum housing despite the coating not being tested against FDA compliance and the nameplate attached non-sealed. However, the hygienic stainless steel housing of the Liquiphant is made of 316L with laser marked nameplate and fulfills therefore additionally SD-2.4.4.2 (i) and withstands high-pressure wash-down up to IP69K (specified in detail in the Technical Information TI).

The finishes of product contact surfaces are in accordance with the definitions according to SD-2.4.4.3 and specified in the Technical Information (TI).

Design of the Liquiphant does minimize the number of connections. A butt welded connection is used, as per SD-3.1.1 (a). The Liquiphant connections use acceptable hygienic design connections, as per SD-3.1.1 (b). The Liquiphant connections are capable of CIP and SIP. Fittings are designed that there will not be any crevices or hard-to-clean areas around the gasketed joint, as per SD-3.1.1 (c). Ferrules and ferrule connections are as short as possible to minimize dead legs, as per SD-3.1.1(d).

All product contact fittings are self-draining when properly installed acc. the manufactures recommendations, as per SD-3.1.1 (e).

Product hold-up volume in the system will not be enlarged by the use of the Liquiphant, as per SD-3.1.2.1 (a).

ASME BPE-2012 Dimensions and Tolerances for Process Components

Fittings of the Liquiphant are manufactured to this part and meet or exceed the pressure ratings shown in Table DT-2-1, and have an ambient temperature bursting strength of at least three times the 100°F rated internal working pressure as shown in Table DT-2-1, as per DT-2.

Materials used in the manufacture of fittings and other process components are conform to one of the material specifications listed in part MM, as per DT-5. For material details refer to the Technical Information (TI).

The Liquiphant can be ordered with typical hygienic clamp unions, as per DT-9.1. Gasket materials will not be supplied. All clamp connections are according the relevant dimensions of ISO2852.

The Liquiphant and its documentation can be visually examined for the following criteria, as a minimum, as per DT-10.1 (a) manufacturer's name, logo or trademark, (b) alloy/material type, (c) description including size and configuration, (d) heat number/code, (e) product contact surface finish symbol, (f) reference to ASME BPE, (h) no damage or other noncompliances.

As per DT-10.3 physical examination a percentage of each lot is physically examined by Endress+Hauser for the following criteria: (a) wall thickness (for weld ends only), (b) outside diameter (O.D.) (for weld ends only), (c) surface finish (as specified), (d) visual.

The Liquiphant is permanently marked on its nameplate with the manufacturer's name, logo, and individual Endress+Hauser serial number. Using the Common Equipment Record additional instrument information can be accessed online, as per DT-11: (a) heat number/ code traceable to material test report for each product contact surface component, (b) material type, (c) manufacturer's name, logo, or trademark, (d) reference to the ASME BPE Standard, (e) product contact surface designation for the appropriate BPE specification.

The sensor and process connection of the Liquiphant are protected with suitable packaging material, as per DT-12.

ASME BPE-2012 Material Joining

As per the recommendation of MJ-2.1, all material for process surfaces conform to AISI 316L (UNS S31603 / EN/DIN 1.4435), all process wetted material conform to Table MM-2.1-1 or MM-2.1.3.

The used filler metal matches Table MM-5.1.2-1, as per MJ-2.2.

The butt joint in which one weld face is a product contact surface has continuous complete weld joint penetration. The weld joints have the product contact surfaces properly purged and protected for the prevention of discoloration or contamination during welding, as per MJ-3.1.

In accordance to MJ-4.1, the process-contact surface of the weld is finished after welding. The welding processes used are limited to the arc or high energy beam (electron beam and laser beam) processes as defined in AWS A3.0. All welding procedures are qualified per ISO15614.

Welder and welding operator performance qualifications are in accordance to ISO9606 / ISO14732.

Process wetted welding of the Liquiphant does not result in a surface that will contribute to microbiological growth and contamination of the product. The welds do not have any discontinuities such as cracks, voids, porosity, or joint misalignment. Welding inspection is accomplished by means of visual inspection.

ASME BPE-2012 Product Contact Surface Finishes

There are in general two surface finishes provided for the Liquiphant:

- Ra max. = 0.38 μm / 15 $\mu\text{in.}$ electropolished per Table SF-2.4.1 SF4,
- Ra max. = 1.5 μm / 60 $\mu\text{in.}$ mechanically polished per Table SF-2.4.1 SF0.

The surface finish to be provided for the instrument covered by this CoC is indicated on page 1.

The interior surfaces of all the process wetted parts of the Liquiphant including sanitary end fittings are mechanically polished per SF-2.4. All mechanically polished surfaces are not undergone any passivation. If ordered the interior surfaces of all the process wetted parts including sanitary end fittings are additionally electropolished per SF-2.5. Minimal material is removed to achieve the indicated surface finishes.

Acceptance criteria for product contact surface finishes are listed in Tables SF-2.2-1 and SF-2.2-2.

The Liquiphant product contact surface finish inspections are made by one or more of the following methods: (a) direct visual inspection, (c) surface roughness measurement (profilometer), as per SF-2.3.

TSE Compliance

Endress+Hauser declares that no components, materials or ingredients of animal origin are being used during the entire production of this Liquiphant including polishing processes.

ASME BPE-2012 Sealing Components

Selected process connections are delivered with a related process seal. For any details concerning these versions and seals refer to the Technical Information (TI).

Hygienic unions provide connections between the process components (Liquiphant and pipe or tank fitting) to ensure the process integrity is maintained. The seals of the Liquiphant are designed as O-rings or static seals as sealing element, as per SG-2.2. O-ring grooves and seal glands are in accordance with the seal manufacturer recommendation for functionality.

O-Rings are flush with the interior surface of the sensor.

The O-rings and static seals are self-aligning and self-positioning.

The performance of the seals is tested and verified according to the service temperature and service pressure and specified accordingly in the Technical Information (TI). The seals are compatible with CIP and SIP media conditions and have a minimum temperature rating meeting the requirements of SD-2.3.1.1, as per SG-3. The seals exposed to process contact fluids are compliant to the FDA and United States Pharmacopeia (USP) directive with regards to USP <87> and USP <88> Class VI on biological reactivity if applicable (compound of O-ring delivered with selected process connection or static seal delivered with selected weld-in adapter, specified in Technical Information TI). The seals are free of molding imperfections, foreign matter on surfaces, molding flash, lubricants, crevices and dead spaces, as per SG-3.3.

Endress+Hauser identifies each process instrument by an individual serial number. Using the instrument documentation or the online Common Equipment Recorder the production data can be identified. All assembled components can be tracked to their particular lot number, at least, as per SG-3.5.

ASME BPE-2012 Metallic Materials

In accordance with MM-2, metallic process wetted parts of the Liquiphant are made of metallic materials as per Table MM-2.1.1 through MM-2.1.3.

The metallic material is manufactured in accordance by one or more of the listed references in MM-4.

The fabrication of the metallic process wetted parts is in accordance to the applicable requirements and guidelines as per MM-5. The filler metal for the process wetted welding matches Table MM-5.1.2-1.

Delta-ferrite content

Process wetted metallic parts of versions of the Liquiphant (specified in Technical Information TI and ordered appropriately) have a delta-ferrite content < 1%. The measurement is performed with a ferriscope. The delta-ferrite content is controlled by one or more of the methods described in Nonmandatory Appendix G. The weldment has been examined for delta ferrite content by a magnetic measuring instrument. If this measurement has been ordered the value will be indicated on page 1 of this CoC.