Herstellererklärung
Manufacturer Declaration

Endress+Hauser
People for Process Automation

Company **Endress+Hauser Flowtec AG, Kägenstrasse 7, CH-4153 Reinach**
declares as manufacturer, that the following product

Product **Promass U 500**

Description	Order code	Extended order code	Mat.Nr.
Promass U DN25 / 1"	DK8014-10D8/0	DK8014-25SBOADFA2	70212574
Promass U DN15 / 1/2"	DK8014-10C2/0	DK8014-15SBOACFA2	70212573
Promass U DN06 / 1/4"	DK8014-10A1/0	DK8014-06SBOABFA2	70212572
Promass U DN04 / 1/8"	DK8014-1098/0	DK8014-04SBOAAFA2	70212568

This manufacturer declaration is exclusively valid for the listed products in delivery status.

The document describes the Certificate of Compliance (CoC) for biopharmaceutical single-use requirements.

CoC Document ID 6407806
The above generated document ID will be generated electronically and is valid without signature.

This manufacturer declaration is exclusively valid for the customer listed in the cover letter of the respective Endress+Hauser sales center and for the listed products in delivery status.

The validity of this manufacturer declaration expires 2 years after the date of issue.

Reinach, 17.5.2024
Endress+Hauser Flowtec AG

Dr. Mirko Lehmann
Managing Director

Dr. Christian Jarms
Head of Division Quality Management

Certificate of Compliance (CoC) for biopharmaceutical single-use requirements.

Compliance to ASME BPE 2022

Hereby we confirm that the product supplied is in compliance to all relevant parts of ASME BPE latest revision (2022) and with the requirements of the order. Furthermore, we declare that during the manufacturing of the product supplied, the valid Endress+Hauser procedures have been followed. Non-specific tests and inspections have been performed and the relevant releases have been given.

Materials of construction of product wetted parts

The product mentioned above consists of process wetted components listed in the table below.

TSE/BSE compliance

All wetted parts do not derive from animal sources and comply with the regulatory requirements of guidance EMA/410/01 Rev. 3.
Furthermore, no grinding and polishing agents of animal origin have been used during the entire production process.

Compatibility with sterilization operations

The materials selected withstand the following sterilization modes without impairing functional performance.
Gamma/e-beam irradiation up to 50 kGy (5.0 Mrad), steam/autoclave 121 °C (250 °F) 60 min (1 cycle).

Assembly and Packaging

Assembly and packaging of the device were carried out in an FDA registered (Samaplast AG registration number # 3008793310) and ISO 13485 certified facility within an ISO 14644-1 Class 7 cleanroom manufacturing suite.

Polishing and surface finish table of process wetted parts

Component	Surface finish Ra_{max}	Polishing[1]	ASME BPE designation
Measuring tube	≤ 0.76 µm (30 µin)	mechanically polished	Acc. to table SF-2.4.1-1 (SF3)
Flow splitter	≤ 0.76 µm (30 µin)	n.a.	Acc. to table SF-3.4-1 (SFP3)

[1] No polishing compound has been used.

Material / compound

Component	E+H Part number	Wetted materials	Material /compound
Seal O-ring	71580323	yes	Silicone VMQ
Measuring tube	71535529	yes	Stainless steel 1.4435 (316L)
Flow splitter	71535528	yes	Polycarbonate Makrolon® Rx1805
Double pouch bags	71597954, 71597955	yes	PET-OPA-PE-PEEL
Blister	71580443	yes	PET

Regulatory / specification

Requirement	Standard	Components					
		Seal O-ring	Measuring tube	Flow splitter	Double pouch bags	Blister	Assembled device
Bioburden	ISO 11737-1 or USP<788> or EP-2.9.19	X	X	X	X	X	X
Cleanliness	ISO 19227:2018	X	X	X	X	n.a.	X
Cytotoxicity	ISO 10993-5 or USP<42>, 2019 Ch. 87	X	n.a.	X	X	X	X
Medical packaging	EN ISO 11607-1	n.a.	n.a.	n.a.	X	X	n.a.
Medical packaging	ISTA-3A	n.a.	n.a.	n.a.	n.a.	n.a.	X
Endotoxin[2]	USP<85> or EP 2.6.14	n.a.	n.a.	n.a.	n.a.	n.a.	X
Sterilization validation[2]	ISO 11737-2 or USP<71>	n.a.	n.a.	n.a.	n.a.	n.a.	X
FDA compliance	FDA 21 CFR 177.2600 or EU 1935/2004	X	n.a.	n.a.	X	X	n.a.

[2] Only applicable after gamma irradiation.

Biocompatibility compliance table

Requirement	Standard	Components					
		Seal O-ring	Measuring tube	Flow splitter	Double pouch bags	Blister	Assembled device
Sensitization	ISO 10993-10	n.a.	X	X	X	X	n.a.
Systemic toxicity	ISO 10993-11	X	X	X	n.a.	n.a.	n.a.
Sample preparation	ISO 10993-12	X	n.a.	n.a.	X	X	n.a.
Reactivity test in vivo	ISO 10993-1 or USP<88> Class VI	X	n.a.	X	X	X	X
Reactivity test in vitro	ISO 10993-5 or USP<87>	X	n.a.	X	X	X	X

Hemolyses & extractable data compliance table

Requirement	Standard	Components					
		Seal O-ring	Measuring tube	Flow splitter	Double pouch bags	Blister	Assembled device
Physical chemical resistance	USP<661>	n.a.	n.a.	X	X	n.a.	n.a.