

Food and Drug Administration (FDA)

CONFIRMATION

SERTO AG confirms that the raw materials of all components in contact with the media of the catalogue products offered by SERTO comply with the listed FDA regulations.

Material	Product	Conformity
	Tube unions - complete range SO and SOL	
Stainless steel	Valves - SO NV 51AXX/E/EB/EL - SO NV 51CXX/E/EB/EL - SO NV 51DXX - SO CV 53BXX / SOL CV 53B XX Quick couplings Series Q50 / Q51	Elastomer seals according to - FDA - 21 CFR 177.2600 PTFE seals according to - FDA - 21 CFR 177.1550
PVDF	Tube unions (complete range)	
	Valves - SO NV 22AXX/E/EB/EL - SO CV 23B21 Stopcocks	PVDF material according to - FDA - 21 CFR 177.2510 Elastomer seals according to
	- SO BV 28AXX	- FDA - 21 CFR 177.2600
	Quick couplings - CO K/KU/KAU and CO T/TA - COP KA/NS and COP TA/NS	PTFE seals according to - FDA - 21 CFR 177.1550
DTEE	Hose nipples (complete range)	FDA 24 CFD 477 4550
PTFE	Polytetrafluorethylene-tube	FDA - 21 CFR 177.1550 FDA - 21 CFR 177.2510
FEP	Polyvinylidenfluoride-tube	FDA - 21 CFR 177.2510 FDA - 21 CFR 177.1550
	Perfluorethylenepropylene-tube	
PFA	Perfluoroalkoxy-tube	FDA - 21 CFR 177.1550
Jacoflon	PTFE tube with stainless steel braid	FDA - 21 CFR 177.1550

For safe, trouble-free operation, the entire system design must be considered when selecting a product. System engineers and users are responsible for the function of the products, their material compatibility, corresponding performance data and application limits as well as for handling, operation and maintenance in accordance with the regulations. No liability claim against SERTO AG can be derived from this confirmation.

Frauenfeld, 01 March 2024

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