

Declaration - FDA

Welded socket



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1 General information

FDA stands for Food and Drug Administration, a U.S. authority. Among other things, this authority issues a regulation on the use of product-contacting materials in the pharmaceutical, food and beverage and cosmetics industries (Code of Federal Regulations CFR).

Always use a suitable, FDA approved process seal.

2 Manufacturer declaration

With explanation to the optional seals

We herewith declare that the material composition of the wetted parts of the following versions of the welded sockets meet the requirements of the Food and Drug Administration.

Process fittings

Tri-Clamp		
ESTC.A1*	ESTC.B1*	ESTC.C1*
ESTC.E1*	ESTC.A3*	ESTC.B3*
ESTC.C3*	ESTC.E3*	

Hygienic fitting		
ESTA.LA3**	ESTA.LB3**	ESTA.LC3**

Cone		
ESTK.KA3	ESTK.KB3	

Bolting		
ESTR.DA1	ESTR.DA3	ESTR.DA8
ESTR.FA1	ESTR.FA3	ESTR.FA8

Thread		
ESTSG.1G***		

This declaration is based on the following certificates:

- Opinion letter of November 22, 2004 on the implemented stainless steels, from the Public Health Service of the Food and Drug Administration, College Park, MD 20740
- The declarations of our seal suppliers/manufacturers regarding conformity with the requirements according to FDA 21 CFR 177. ****

Furthermore, it is the responsibility of the operator to ensure compliance with any additional food and process-specific requirements.

3 Manufacturer declaration

Without explanations to the seals

We herewith declare that the material composition of the wetted parts of the following versions of the welded sockets meet the requirements of the Food and Drug Administration.

Process fittings

Tri-Clamp		
ESTC.AX*	ESTC.BX*	ESTC.CX*
ESTC.DX*	ESTC.EX*	ESTC.FX*
ESTC.GX*		

DRD		
ESTD.AAXX		

Bolting		
ESTR.DAX	ESTR.FAX	ESTR.FBX
ESTR.GAX	ESTR.GBX	ESTR.IAX
ESTR.JAX		

Hygienic fitting		
ESTA.LAX**	ESTA.LBX**	ESTA.LCX**

Cone		
ESTK.KAX	ESTK.KBX	

This declaration is based on the following certificates:

- Opinion letter of the Public Health Service of the Food and Drug Administration on the implemented stainless steels (College Park, MD 20740 of 22.11.2004)

Furthermore, it is the responsibility of the operator to ensure compliance with any additional food and process-specific requirements.



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