

# FDA conforming materials and biocompatibility.



Foodstuff and medical technology place special requirements on physiological suitability and durability.

## FDA Conformity

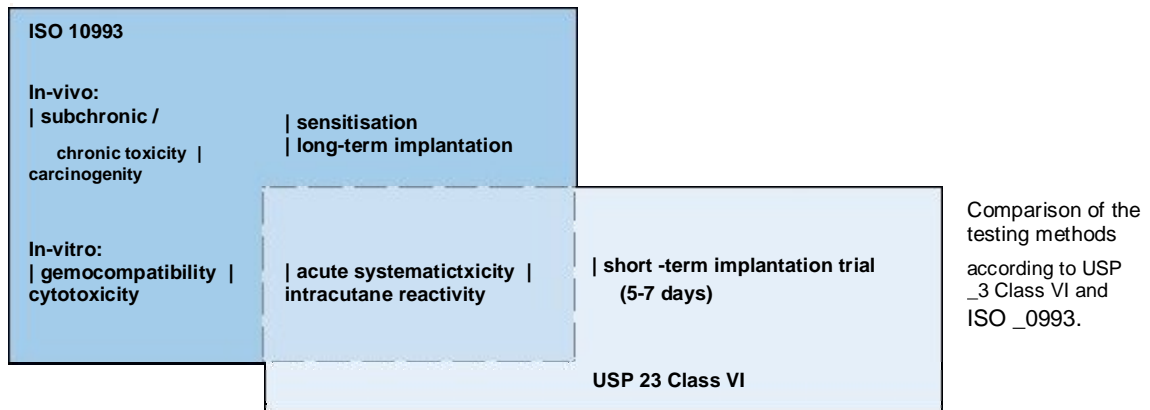
The American Food and Drug Administration (FDA) inspects the suitability of materials for contact with food. Raw materials, additives and properties of plastics are specified by

the FDA in the „Code of Federal Regulations“ CFR \_\_. Materials that meet the relevant requirements are regarded as FDA-conforming.

## Biocompatibility

Biocompatibility is the measure of the compatibility of a material with the tissue or physiological system of the patient. Assessment takes place after a number of investigations as defined in USP (U.S. Pharmacopeia) Class VI or ISO \_0993. Biocompatibility depends not only on the type of material, but also on:

- | Where it is used (skin, mucus membranes/ blood, tissue)
- | The intended function (superficial contact with the body, contact with the interior of the body, product for implantation)
- | The length of time that the material remains in the body (< \_\_ hours, < 30 days, indefinitely)



Material	DIN-Abbreviation	Raw material	FDA conformity	Biocompatibility
TECAPEEK CLASSIX™	PEEK	Invibio® PEEK®	x	x
TECAPEEK MT	PEEK	Victrix® PEEK®	x	(_)
TECAFLON PTFE	PTFE	Hostafion, Teflon	x	(_)
TECATRON MT	PPS	Fortron®	x	(_)
TECASON E	PES	Radel® A	x	-
TECAPEI MT	PEI	Udel®	x	(3)
TECASON P MT	PPSU	Radel® R	x	(_)
TECASON S	PSU	Ultem®	x	(_)
TECAFLON PVDF	PVDF	Solef, Kynar	x	(_)
TECAMAX SRP	PPP		in testing	
TECANAT	PC	Lexan, Makrolon	x	(_)
TECADUR PET, TECAPET	PET	Arnite, Crastin	x	-
TECAMID 66	PA 66		x	(_)
TECAFORM AH MT	POM-C	Celcon	x	(_)
TECAPRO MT	PP		x	(3)

(\_) Applies to MT black, other colours on request ( )  
On request  
(3) Applies to natural, colours on request

\* FDA conformity and biocompatibility apply to natural materials. The pigments used are tested for their suitability according to the FDA regulations. Biocompatibility is not a material specification, and requires prior testing, and if necessary special production.