

REGULATORY AFFAIRS - Product Information

FIL-A-GEHR – PEEK

We confirm that the raw material, which we use for manufacturing our semi-finished products fulfils the requirements below:

European Directives	10/2011/EC, 1935/2004/EC
Good Manufacturing Practice	2023/2006/EC
Food & Drug Administration	FDA - CFR 21, 177.2415
In vitro cytotoxicity test	ISO 10993-1
RoHS (<i>Restriction of Hazardous Substances</i>)	2015/863/EC, 2011/65/EC
REACH (<i>Registration, Evaluation, Authorisation and Restriction of Chemicals</i>)	1907/2006/EC
Military	Mil P-46183 T1

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The present certificate corresponds with our actual knowledge. However customers should verify regulatory status periodically, if needed.