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PRODUCT CHANGE NOTIFICATION

DOC-PCNWEB-002, Rev. A

PCN Number	<u>220130</u>
PCN Title	<u>Chemglass Life Sciences Certificate of Compliance Document</u>
Notification Date	<u>1/30/2022</u>
Implementation Date	<u>1/30/2022</u>
Part Description	<u>Material Certificate of Compliance</u>
Affected Part Number(s)	<u>None - Document change only.</u>
Change Description	<u>Restated Footnote 1: USP Type 1 Class A Borosilicate Clear Glass conforms to Federal Specifications ASTM E-438.</u> <u>Removed section from Footnote 2: Colorant components that are FDA regulated comply with 21 CFR 177.3297 (Colorants for Polymers)</u> <u>Restated Footnote 5: Virgin PTFE is manufactured of Class VI materials which conform to specifications in FDA 21 CFR 177.1550</u> <u>Restated Footnote 6: 316L Stainless Steel surface of wetted areas have a finish no greater than RA20 after electropolishing. All non-wetted surfaces has a surface finish no greater than RA40 after electropolishing.</u> <u>Removed Footnote for Glass filled PTFE/TFE items conform to ASTM D4745-11 specifications for Type 1, Class 2 Filled polytetrafluoroethylene (PTFE) materials.</u>
Reason for Change	<u>A needed re-evaluation and update to material compliance Information of our material Certificate of Compliance Document.</u>
Performance Impact	<u>More accurate information on customer product material requests.</u>
PCN Correspondence	<u>QC@cglifesciences.com</u>

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FORM - FIT - FUNCTION DEFINITIONS

FORM: Refers to such characteristics as external dimensions, weight and size of a part or assembly.

FIT: Refers to the ability of the part or feature to connect to, mate with, or join to another feature or part within an assembly.

FUNCTION: Is a criteria that is met when the part performs its stated purpose effectively and reliably.