

CEDI Modules

LX Materials of Construction

During the winter of 2015 there was a worldwide shortage of polysulfone, the raw material used for molding our LX-X and LX-HI spacers,. Due to this shortage, we were experiencing longer lead times on material, higher costs, and are still receiving limited allocations of the polysulfone material. Comparable materials such as polyphenylsulfone are similarly restricted in supply.

This has forced us to transition production of our LX-X product to a NSF-rated ^[d,f] CPVC spacer to maintain our current availability for LX-X and not impact the availability of LX-HI with polysulfone spacers.

Neither FDA, USP nor EU define specific regulations for the materials used in the purification of pharmaceutical grade water. The closest analogous standards are for materials that can contact food, drinking water, or be used to manufacture medical devices. Below is a summary of regulatory status for raw materials used in the LX-X and LX-HI. Additional details are provided in IONPURE tech bulletin IPTB-2016-04. These products may not meet all aspects of the European Union (EU) 10/2011 directive for food contact. They do comply with NSF-61 and NSF-14 for drinking water, with LX-HI also meeting ISO 10993^[c] standard for medical devices and EU 2002/72/EC. We believe that makes them both suitable for use in pharmaceutical water systems.

LX-HI:

Spacers comply with: 21 CFR 177; ISO 10993 (Parts 5, 10, 11, 18); NSF 51; NSF 61, EU 2002/72/EC and 2003/11/EC

Other wetted materials comply with: 21 CFR 177 or 21 CFR 173

LX-X:

Spacers comply with: NSF 14; NSF 61

Other wetted materials comply with: 21 CFR 177 or 21 CFR 173

LX-EU:

Spacers comply with: 21 CFR 177; ISO 10993 (Parts 5, 10, 11, 18); NSF 51; NSF 61, EU 2002/72/EC, 2003/11/EC, and 89/109/EEC

Other wetted materials comply with: 21 CFR177

Currently, our suggestion therefore, is that customer requests that require FDA 21 CFR 177^[a] use our LX-HI series modules, or the following NEW EU-specific LX-EU series.



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W3T387617	IP-LXM4EU-4
W3T387618	IP-LXM10EU-4
W3T387597	IP-LXM18EU-4
W3T387598	IP-LXM24EU-4
W3T387600	IP-LXM30EU-4
W3T387621	IP-LXM45EU-4

Reference documents:

- [a] 21 CFR 177 – Indirect Food Additives: Polymers
- [b] 21 CFR 173 – Secondary Direct Food Additives Permitted in Food for Human Consumption
- [c] ISO 10993 – Biological Evaluation of Medical Devices (Parts 5, 10, 11, 18)
- [d] NSF/ANSI 14-2015 – Plastic Piping System Components and Related Materials
- [e] NSF/ANSI 51-2015 – Food Equipment Materials
- [f] NSF/ANSI 61-2015 – Drinking Water System Components – Health Effects

With kind regards,

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