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## 7 Appendices

### *Annex 1: FDA Compliance Summary of Liqui-Cel® Membrane Contactor*



Sept 06, 2013

#### FDA Compliance Summary of Liqui-Cel® Membrane Contactors

This letter is a confirmation that all wetted components of the 2.5 x 8, 4 x 13, 4 x 28, 6 x 20, and 10 x 28 high purity Liqui-Cel® Extra-Flow Membrane Contactors, when used in accordance with recommendations given in our product literature for treatment of process water, alcoholic and non-alcoholic beverages, and aqueous, acid and non-acid food products at and below ambient temperatures, are in compliance with all relevant FDA regulations as specified in Title 21 of the Code of Federal Regulations. Our 6 x 28 Membrane Contactors comply with all uses stated above except for use with alcoholic beverages. Note that the 6 x 20 Industrial contactor in PVC housing and 10-inch Industrial contactor are not FDA compliant.

#### Contactor Components Fall Within and Meet the Following Title 21 Code of Federal Regulations Chapter

| Component              | Materials                 | Chapter            |
|------------------------|---------------------------|--------------------|
| Hollow Fiber Array     | Polypropylene             | 177.1520           |
| Center Tube            | Polypropylene, ABS*       | 177.1520           |
| Outer Protective Mesh  | Polypropylene             | 177.1520           |
| O-Rings                | EPDM, Viton, Buna-N       | 177.2600           |
| Retention Ring, 4-Inch | Teflon                    | 177.1550           |
| Potting Compound       | Epoxy                     | 177.1210           |
| Potting Compound       | Polyethylene              | 177.1520           |
| Housing, Plastics      | Polypropylene, PVDF, ABS* | 177.1520, 177.1020 |
| Housing, Steel         | 316L SS                   | Not Applicable**   |

\* ABS used in 6 x 28 Contactors is not approved for use with alcoholic beverages.

\*\* We certify that our SS Housings are 316L SS, which is acceptable for use in Pharmaceutical and in Food & Beverages applications.

Regards,

Mark Norton  
Plant Manager

Membrana-Charlotte | A Division of Celgard, LLC | 13800 South Lakes Drive | Charlotte, North Carolina 28273 USA  
704-587-8500 | www.membrana.com

A **POLYPURE** Company



*Annex 2: Membrana-Charlotte EU Food Contact Declaration*



Mar 09, 2015

**Membrana – Charlotte EU Food Contact Declaration**

Liqui-Cel® 2.5 x 8, 4 x 13, 4 x 28, 8 x 20 SS, 8 x 40 SS, 8 x 80 SS and 10 x 28 SS Contactors are non-hazardous articles manufactured from high quality raw materials in accordance with the Membrana-Charlotte product specification and applicable regulatory requirements. In addition, Membrana-Charlotte manufacturing processes are ISO 9001 and 14001 certified.

Membrana-Charlotte has successfully tested Liqui-Cel® 2.5x8, 4x13, 4x28, 8x20 SS, 8x40 SS, 8x80 SS and 10x28 SS Contactors plastic raw materials and rubber seals for compliance with EU Regulation for Food Contact: EC No. 1935/2004 and No. 10/2011.

The overall migration limit has to be controlled in the food processing system. It is the end users' responsibility to check same by modeling or appropriate Specific Migration Tests for the suitability of contact with different food types and various end-use conditions. We only certify the Liqui-Cel® products in the condition as sold.

Product Safety and Environmental Management inquiries are welcome and should be forwarded to this office.

A handwritten signature in black ink, appearing to read "Mark Norton".

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