Declaration of Conformity

Ultrafilter filters are manufactured from polypropylene hardware, support and drainage layers and Polypropylene media. Ultrafilter only use approved materials sourced from the European Community or the United States.
PF-PP filter components **meet or exceed European Legislation** encompassed by **EC1935.2004,EC2002.72** and amendments. The filter hardware is fusion welded with heat; noglues or resins are used in the process. Meet the requirement and criteria of **USP <85>**, **USP <87>**, **USP <88>**, **USP<643>**, **USP<645>** and **USP<788>**. We declare under our sole responsibility that the product listed below:

MATERIALS OF CONSTRUCTION	
Filter media	Polypropylene
Support	Polypropylene
Core & Cage	Polypropylene
Adaptor & End Caps	Polypropylene
Seal Material	EPDM/Silicone Elastomer

Declaration

PF-PP Series Filter Cartridge comprise of materials that meet regulatory and legislative requirements and guidelines for pharmaceutical contact in that:

Europe
PF-PP Series Filter Cartridge meet the requirements for pharmaceutical contact as detailed in European.
Our suppliers state that the polymeric materials used to produce this product are made from monomers and additives listed in Annex I of Commission Regulation (EU) Number 10/2011 with its amendments Materials and articles intended to come into contact with pharmaceutical materials (excluding seals).

Migration testing of cartridges employing the same materials of construction as above, has been performed, and met migration criteria after flushing and in flow conditions.
Tested as 10" PF-PP-D100307-B-V In:
– Simulant B (3% acetic acid) for 2 hours at reflux,
– Simulant D1 (ethanol 50%) for 2 days at 60 °C.

USA
The materials of construction meet the FDA requirements for pharmaceutical contact use as detailed in Code of Federal Regulations:
• Polypropylene to 21 CFR section 177.1520
• EPDM/Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils).
Note: Polybutylece terephthalate was encapsuled by polyproplene, and would not come into contact with pharmaceutical materials.

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

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Declaration of Conformity

Good Manufacturing Practice (GMP) and Hazard Analysis and Critical Control Points (HACCP)

Ultrafilter confirms that the product manufacturing environment, for the above product at our site, is in-line with the principals of pharmaceutical contact materials GMP as detailed in Regulation 2023/2006.
Ultrafilter filters are produced in an ISO Class cleanroom by fully gowned staff to reduce the risk of contamination. Ultrafilter's filters are rinsed in endotoxin-free water, with daily checks of endotoxin levels using the Limulus Amebocyte Assay. All polymer materials in contact with rinse water are approved to ensure that they meet appropriate legislation for pharmaceutical contact materials. Ultrafilter retains records of allprocesses and materials for each cartridge filter for a minimum of 5 years.

International and National Standards Organisation Approval of Ultrafilter's Quality Management System

Ultrafilter's Quality Management System has been certified by a German approved inspection to meet ISO 9001:2015 and ISO 14001:2015 for the manufacture of filtration products.

Hilden, July 2022

Dustin Dean Kronsbein
Managing Director

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