Medical Reference Guide, July 2022

Vivak® Med, Exolon® Med, Inspria® Med
Guidance on use of Exolon Group products in a Medical Application

All sheets from Exolon Group which are in this document referred to as “Medical Grade” **(Exolon® Med, Vivak® Med** and **Inspria® Med)** are produced out of resins which meet certain biocompatibility test requirements of USP Plastics Class VI and ISO 10993-1 with human tissue contact times of 30 days or less. These tests include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (sub-acute), implantation and hemocompatibility.

These products cannot be used for the following types of medical applications:

a. cosmetic, reconstructive, or reproductive implant applications
b. any other long-term implant applications
c. applications involving contact with or storage of human tissue, blood, or other bodily fluids, for more than 30 days
d. any critical component in a medical device that supports or sustains human life.

The suitability of a product in a given end-use environment depends upon various conditions including, without limitation, chemical compatibility, method of manufacture, temperature, part design, sterilization method, residual stresses, and external loads. It is the sole responsibility of the manufacturer of the final end-use product to determine the suitability (including biocompatibility) of all raw materials and components, including any Exolon Group products, in order to ensure that the final product:

- meets relevant biocompatibility requirements and is otherwise safe for its end-use
- performs or functions as intended
- is suitable for its intended use
- complies with all applicable FDA and other regulatory requirements.

Medical Grade sheets from Exolon Group are a semi-finished product and not a final end-use product. The end-use product itself is beyond our control. The biocompatibility assessment of final products made from Medical Grade sheets from Exolon Group or the compatibility of such products for their use in a medical application cannot be based on tests performed on the original polymer or on the sheets. It is the sole responsibility of the manufacturer of the final product to conduct all necessary tests (including biocompatibility tests) and inspections and to evaluate the final product under actual end-use requirements.

The designation as “Medical Grade” does not mean that Exolon Group has determined the product is for use in any particular Medical Application. Only the purchaser who utilizes a medical grade product from Exolon Group can determine if the product is suitable for use in a particular medical application or final end-use product, by conducting all necessary testing and evaluation to support such a determination.
In case the final product falls under the application of a medical device and will be marketed in Europe, the

final manufacturer will be solely responsible for ensuring that the final product fully complies with the Medical Devices Regulation (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017).

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