

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

The manner in which you use and the purpose to which you put and utilize our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you test our products, technical assistance, information and recommendations to determine to your own satisfaction whether our products, technical assistance and information are suitable for your intended uses and applications. This application-specific analysis must at least include testing to determine suitability from a technical as well as health, safety, and environmental standpoint. Such testing has not necessarily been done by Exolon Group. The biocompatibility testing referenced above cannot assure the biocompatibility of final or intermediate products made from Exolon Group products or the suitability of such products for their use in a Medical Application, i.e., the test data cannot be used to conclude that any medical devices manufactured from the Exolon Group products meet the necessary requirements of ISO Standard 10993-1. It is the sole responsibility of the manufacturer of final end-use product to conduct all necessary tests (including biocompatibility tests) and inspections and to evaluate the final product under actual end-use requirements. Unless we otherwise agree in writing, all products are sold strictly pursuant to the terms of our standard conditions of sale which are available upon request. All information and technical assistance is given without warranty or guarantee and is subject to change without notice. It is expressly understood and agreed that you assume and hereby expressly release us from all liability, in tort, contract or otherwise, incurred in connection with the use of our products, technical assistance, and information. Any statement or recommendation not contained herein is unauthorized and shall not bind us. Nothing herein shall be construed as a recommendation to use any product in conflict with any claim of any patent relative to any material or its use. No license is implied or in fact granted under the claims of any patent.

The logos for Exolon, Inspria, and Vivak. "exolon" is in red, "inspria" is in blue, and "vivak" is in dark blue. Each logo has a registered trademark symbol (®) to its upper right.

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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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