

MEDICAL APPLICATION POLICY

TSRC will not supply VECTOR SEBS under ordinary terms to firms using such materials for medical applications in devices classified as Class IIb or Class III per European Union (EU) Medical Device Regulation (MDR), or any devices that present equivalent levels of risk in other regulatory jurisdictions.

TSRC declares that TSRC products may not be used in medical applications involving implantation in the human body or performant contact (more than thirty days) with internal human body fluids or tissues.

As shown on the enclosed "Medical Declaration," TSRC has conducted testing on its VECTOR SEBS products for purposes of assessing the potential use of the product in Class I or Class IIa medical devices in the EU (or any devices that present equivalent levels of risk in other regulatory jurisdictions).

TSRC product names, trademarks and the TSRC name shall not be used in conjunction with either permanent or temporary medical devices, and customers should not represent to others that TSRC permits, recommends, or endorses the use of our materials in medical devices.

It is solely the responsibility of the medical device manufacturer to determine that TSRC products are safe, lawful, and technically suitable for the manufacturer's intended use. TSRC MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, CONCERNING THE SUITABILITY OF ANY TSRC PRODUCTS FOR USE IN MEDICAL APPLICATIONS.

Please notify all appropriate individuals in your organization of this medical policy.

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