

**3M Electronics Materials Solutions Division (EMSD)****GLOBAL EMSD POLICY REGARDING THE SALE AND USE OF PRODUCTS FOR MEDICAL AND PHARMACEUTICAL APPLICATIONS****Background**

EMSD products are intended for industrial or professional use only. EMSD products are not intended for use in medical and pharmaceutical applications or products. The medical and pharmaceutical market for products has unique business and regulatory demands. For example, most EMSD products are manufactured to industrial or commercial specifications in compliance with ISO 9001:2008 and certain other recognized industrial quality standards. These products, however, are not certified to or manufactured in accordance with current good manufacturing practice (CGMP) requirements for medical devices or pharmaceuticals or other similar quality systems, regulations, or standards that may be expected or required for medical or pharmaceutical applications.

**Policy Statement**

EMSD is willing to sample, support and sell 3M products for the invention, development and improvement in medical and pharmaceutical applications and products that enhance or preserve life provided the use and sale of such 3M products complies with this policy and 3M corporate policies and is consistent with 3M's commitment to quality and reliability.

- 3M Products Sold or Sampled as Medical Devices or Pharmaceuticals. EMSD **will not** knowingly sample, support or sell 3M products for use in any medical or pharmaceutical application in which the 3M product itself (i.e., in the same or substantially the same form available from 3M) is intended for use as a medical device or pharmaceutical (i.e., where the 3M product is intended for use as a single stand-alone component in any medical application or for use as a medical device or pharmaceutical).
- 3M Products Sold or Sampled as Component of Finished Product Intended for Implant into the Human Body. EMSD **will** only sample, support, or sell 3M products for use in medical and pharmaceutical applications that will be implanted, either temporarily or permanently, into humans **if** (i) EMSD deems such decision advisable and acceptable in its good business judgment, (ii) is satisfied that the medical customer is committed to excellence in quality and manufacture, and (iii) such opportunity is approved by 3M EMSD management and the 3M Corporate Environmental Health and Safety Committee, when applicable.
- 3M Products Sold or Sampled as Component of Finished Product for Non-Implant Applications. EMSD **will** only sample, support, or sell 3M products for use in non-implant medical and pharmaceutical applications **if** (i) EMSD deems such decision advisable and acceptable in its good business judgment and (ii) is satisfied that the medical customer is committed to excellence in quality and manufacture by information presented in the EMSD application checklist tool.

EMSD, in its sole discretion, reserves the right to sample, support and sell a 3M product for medical and pharmaceutical application.

Each user or customer that elects to sample or purchase a 3M product for a medical or pharmaceutical application is responsible for evaluating and determining that the 3M product is suitable and appropriate for its particular use and intended application. The conditions of evaluation, selection, and use of a 3M product can vary widely and affect the use and intended application of a 3M product. Because many of these conditions are uniquely within the user's and customer's knowledge and control, it is essential that the user and customer evaluate and determine whether the 3M product is suitable and appropriate for a particular use and intended application, and complies with all applicable laws, regulations, standards, and guidance.

## Examples

**Examples of products or applications that EMSD has decided to sample, support or sell** under this policy include, but are not limited to, the following:

- Precision cleaning of medical devices
- Deposition of silicones or other lubricants on hypodermic needles, surgical staples, and other medical devices
- Swelling of silicone tubing
- Use as diagnostic testing fluids or reagents
- Use as a drawing lubricant for drawing wire or metals
- Use of adhesive in construction of a medical device for an outside the body application
- Copper interconnects and cable assemblies for medical imaging equipment, hospital beds and diagnostic equipment
- Flexible printed circuits for medical imaging equipment and hearing aid
- Component transport products for components assembled into medical devices

**Examples of products or applications that EMSD has decided not to sample, support, or sell** under this policy include, but are not limited to, the following:

- Flexible interconnect circuits or assemblies in direct contact with the human body and fluids
- Circuits for use in life sustaining applications
- Lung perfusion materials
- Blood substitutes
- Eye surgery solutions
- Aerosol inhalers
- Contrast agents
- Heat transfer within implantable devices where the customer's product (medical device or pharmaceutical) comprises only the 3M product
- Preparation and storage of viable biological tissue (e.g. sperm and ovum cells)
- Fluorinated anti-static agents where the agent is mobile or may be leached from the device or substrate)

The foregoing examples should not be relied upon in making any decision under this policy and each individual EMSD product must undergo the EMSD Review Process.

## Questions

Questions about this policy and its applicability to a specific EMSD product should be directed to:

EMSD Performance Fluids, Novec™ Products, Battery Additives and Components  
Attention: Jay Schulz, MRD Product Steward, [jfschulz@mmm.com](mailto:jfschulz@mmm.com); 651-733-5463

EMSD Adhesives and Tapes, Microfinishing Systems  
Attention: Dr. Stephen Ezzell, Sn Regulatory Specialist, [saezzell@mmm.com](mailto:saezzell@mmm.com) ; 651-737-4165

EMSD Flexible, Interconnect Circuits  
Attention: Dr. Justine Mooney, Technical Manager, Interconnect & Flex Lab, [jamooney@mmm.com](mailto:jamooney@mmm.com)  
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