Myths & Facts About Medical Lubricants

Not all lubricants are suitable for medical applications. To help you reduce risk and pick the right lubricant for your application, we've debunked the most common myths surrounding medical lubricants.

MYTHS	vs.	FACTS
There is an official medical-grade certification for lubricants.		Official medical-grade certifications do not exist for lubricants. Nye Lubricants is ISO 13485:2016 certified; meaning we have a quality management system in place that consistently meets regulatory requirements for medical devices and related services.
All food-grade lubricants are safe to use in medical devices.		Per the FDA, food-grade lubricants are only approved for incidental food contact up to 10 ppm. They are not required to pass biocompatibility tests like ISO 10993 that ensure a lubricant can safely come into indirect contact with the skin or body cavity.
Lubricants only reduce friction and wear within medical devices.		Lubricants can add value to your application by creating an environmental seal, controlling precision motion, enhancing tactile feel and reducing noise and vibration in medical devices.
Medical lubricants pose a greater risk than benefit to my application.		Properly selected lubricants improve device performance and biocompatibility testing helps mitigate risks to the manufacturer, device user and the patient.
Lubricants for medical devices must be approved by a government organization before use.		US goverment agencies do not regulate medical device material suppliers. However, selecting a lubricant designed for and tested to device standards can help reduce risk to device approval.

Since 1844 Nye® Lubricants

NyeMed®

Specialty Gels & Fluids Formulated for Medical Applications

The extremely diverse and innovative global MedTech industry challenges suppliers to solve diverse problems, often requiring a custom product or solution. As a custom formulator and manufacturer of lubricants, motion control gels, and specialty fluids, utilizing a broad range of material classes and specialty packages, Nye is uniquely positioned to serve the needs of this growing industry with our NyeMed® product line.

Backed by Biocompatibility Data

Our NyeMed® product line is backed by ISO 10993 Cytotoxicity, Skin Irritation, and Acute Systemic Toxicity data to reduce risk for our customers. Food-grade lubricants are not validated for incidental direct contact or injection into the body cavity and could cause adverse reactions.

ISO 13485 Certified

Nye became ISO 13485 certified in 2015 to reassure our customers that our gels and fluids are manufactured to the same standards as medical devices. The ISO 13485:2016 certification specifies requirements for a quality management system adopted by an organization which needs to demonstrate its ability to manufacture medical devices, and provide related services, that consistently meet customer and regulatory requirements applicable to medical devices. Nye is currently the only lubricant company to hold this certification.

Fully Qualified

Nye fully qualifies all NyeMed® products and uses the ISO 13485 requirements to complete a comprehensive risk assessment that informs the development of manufacturing procedures, specifications, and tolerances. These processes are strictly followed and documented throughout manufacturing.

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