



M. HOLLAND MEDICAL, PHARMACEUTICAL AND RELATED APPLICATIONS POLICY

Notification to customers who intend to use plastics distributed by M. Holland Company (“M. Holland”) in medical devices, pharmaceutical, in-vitro diagnostic, or related applications:

M. Holland distributes a wide variety of high-quality plastic raw materials that may be able to satisfy the technical specifications of medical device, pharmaceutical, in-vitro diagnostic, and related applications.

M. Holland DOES NOT supply any materials for use in any article or medical device to be permanently implanted in or having permanent or long-term contact with the human body, including its internal bodily fluids or tissues. ANY SUCH USE IS WITHOUT M. HOLLAND’S CONSENT, AND M. HOLLAND EXPRESSLY FORBIDS THE USE OF THE RAW MATERIALS IT SUPPLIES IN IMPLANTABLE DEVICES AND DISCLAIMS ALL LIABILITY FOR ANY INJURY, DEATH, LOSS OR DAMAGE IN ANY WAY ARISING OUT OF OR RELATING TO SUCH USE OF THE MATERIALS IT SUPPLIES.

Subject to an evaluation, M. Holland is prepared to supply plastic raw materials for medical devices, solid dosage pharmaceutical applications and in-vitro diagnostics rated as FDA and EU Class I risk classifications.

Subject to an evaluation, M. Holland is prepared to supply plastic raw materials for medical devices (excluding implants) and packaging of parenteral and ophthalmic pharma products, including inhalers and auto-injectors, rated as FDA and EU Class II, IIa, and IIb risk classifications.

Applications that are briefly or temporarily implanted in the human body or that come into bodily fluid, tissue or intimate drug contact require a signed M. Holland Medical Disclaimer and Hold Harmless Agreement.

M. HOLLAND COMPANY MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OR FITNESS OF ANY RAW MATERIALS IT SUPPLIES FOR USE IN MEDICAL, PHARMACEUTICAL, DIAGNOSTIC AND RELATED APPLICATIONS, OR THE SUITABILITY OR FITNESS OF ANY MEDICAL DEVICE OR OTHER PRODUCT MADE, WHOLLY OR IN PART, FROM ANY RAW MATERIALS IT SUPPLIES FOR ANY PARTICULAR PURPOSE. THE DECISION ON THE USE OF RAW MATERIALS SUPPLIED BY M. HOLLAND FOR A SPECIFIC APPLICATION IS SOLELY AT THE BUYER’S RISK. IT IS THE RESPONSIBILITY OF THE MEDICAL DEVICE, PHARMACEUTICAL, IN-VITRO DIAGNOSTIC OR OTHER MANUFACTURER (BE IT THE BUYER OR A THIRD PARTY) TO: (1) DETERMINE THAT THE MEDICAL DEVICE, PHARMACEUTICAL, DIAGNOSTIC OR RELATED APPLICATION MANUFACTURED USING THE RAW MATERIALS SUPPLIED BY M. HOLLAND IS SAFE, LAWFUL AND TECHNICALLY SUITABLE FOR THE INTENDED USE, PERFORMS OR FUNCTIONS AS INTENDED AND COMPLIES WITH ALL APPLICABLE LEGAL AND REGULATORY REQUIREMENTS; (2) CONDUCT ALL NECESSARY TESTS, INSPECTIONS, AND EVALUATIONS OF THE MEDICAL DEVICE, PHARMACEUTICAL, DIAGNOSTIC OR RELATED APPLICATION UNDER ACTUAL END-USE REQUIREMENTS; AND (3) ADEQUATELY ADVISE AND WARN PURCHASERS, USERS AND LEARNED INTERMEDIARIES (SUCH AS PHYSICIANS) OF PERTINENT RISKS, AND FULFILL ANY POST-MARKET SURVEILLANCE AND OVERSIGHT OBLIGATIONS.