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RISK ASSESSMENT FORM

Medical/pharmaceutical application

The purpose of this form is to become familiar with the specific requirements in the medical/pharmaceutical segment, thereby ensure a proper MOL polymer grade selection intended for medical/pharmaceutical application.

General information

Processing company:

Brand owner/manufacturer:

MOL grade name:
(one form per grade)

Final product:
(one form per application)

Customer´s name:

Phone:

Email:

Date:

Description of the final product and contained material:

Countries or regions in which the final product will be sold:

Please complete either section 1 (Medical device) or section 2 (Pharmaceutical packaging) or section 3 (In-vitro diagnostic and laboratory applications). Please provide further detail in section 4 (Additional information) if the application is not classified in any of these sections.

Section 1 — Medical device

☐ Medical device in accordance with Regulation (EU) 2017/745

Please tick "yes" if this a Class I (EU) medical device or if it belongs to an equivalent class in the USA or any other country. ☐ Yes

Please complete the following sections if this is a Class 2 medical device or higher.

1. Classification:	EU	USA	Other
2. Duration of use:	☐ temporary (<60 min)	☐ short-term (<30 days)	☐ long-term (>30 days)
3. Invasiveness:	☐ non-invasive (please describe in more detail)		
	☐ body fluid storage/line for an infusion	☐ change in the composition of body fluids for an infusion	☐ other
	☐ invasive (please describe in more detail)		
	☐ with reference to the opening in the body	☐ surgically invasive	☐ implantable device
4. Physical contact (please describe in more detail):			
	☐ contact with the heart, central nervous system or blood circulation	☐ skin contact	
	☐ contact with mucosa	☐ contact with blood	
	☐ contact with tissue/bone/dentine	☐ other contact	

Section 2 — Pharmaceutical packaging

☐ Pharmaceutical packaging - plastic packaging for medicinal products or medical devices

Type of administration:	☐ oral	☐ topical	☐ inhalation	☐ in the eye
	☐ parental	☐ intravenous	☐ other	
Pharmaceutical form:	☐ solid	☐ not solid		
Type of Packaging:	☐ primary packaging	☐ secondary packaging		

Section 3 — In-vitro diagnostic and laboratory applications

☐ In-vitro diagnostic article in accordance with Regulation (EU) 2017/746

Risk category: A ☐ B ☐ C ☐ D ☐

Does the plastic product that is being used come into direct contact with blood, tissue or reagents?

Yes ☐ No ☐

☐ General laboratory supplies/consumables

Section 4 — Additional information

Please list additional tests and documentation here that the client has requested. Does the application require sterilisation? If yes, which method?

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