

## **STANDARD TERMS AND CONDITIONS OF SALE**

### **1. GENERAL**

Where not in conflict with the terms set forth in the Sales Order Confirmation, these Standard Terms and Conditions of Sale provided herein form an integral part of the confirmation of a contract of sale concluded between the Vinmar or affiliated company identified as the Seller therein ("Seller") and the party identified as the Buyer therein ("Buyer") (the Standard Terms and Conditions of Sale and the Sales Order Confirmation are collectively referred to herein as the "Order" or "Contract"). The terms of the Contract form a single agreement between the parties. Seller has agreed to sell the products described in the Order (the "Products") only on the terms and conditions contained in Seller's Order and on no other terms and conditions unless Seller's Order is amended by Seller in writing. If the Buyer issues any contract document in connection with this Order, Seller rejects and refuses to accept as part of the Order, all provisions in the Buyer's contract document which conflict with, add to, or subtract from the terms and conditions of Seller's Order. Written acknowledgement of Buyer's contract document by Seller will not constitute an agreement in writing to any additional or different terms unless expressly so stated in the acknowledgement and then only to the extent stated.

### **2. ACKNOWLEDGEMENT**

In addition to any other acknowledgement by the Buyer, the delivery of a letter of credit to Seller to pay for the Products in accordance with the Order shall constitute a definite acknowledgement by the Buyer that the Contract is subject only to the terms and conditions of Seller's Order and to no other terms and conditions, except as Seller's Order may be amended by Seller in writing to record some additional agreement between Seller and the Buyer.

### **3. TERMINATION/CANCELLATION/SUSPENSION OR STOPPAGE OF PERFORMANCE OR DELIVERY**

The Order may not be terminated in whole or in part by Buyer without the prior written consent of Seller and the payment of reasonable adjustment charges. In case of breach of contract failure or repudiation by Buyer in the performance of any of its obligations under the Order (including, without limitation), failure to pay for a shipment/delivery; or receivership or bankruptcy of Buyer; or if Buyer shall make an assignment for the benefit of creditors; or shall go out of business, or if Seller shall in good faith deem payment of Buyer's obligations hereunder to be insecure, then in any such event, at its option, Seller may (a) cancel the Order or any part thereof; (b) suspend or stop performance of its obligations hereunder or delivery of the Products or (c) place Buyer on a cash-on-delivery basis without prejudice to or waiver of any other rights under the Order, at law or equity; it is further agreed that in any such event, Seller may estimate its reasonable damages and may apply any down payment or balance thereof then on hand, or set-off any amounts otherwise owed by Seller to Buyer pursuant to this Contract or any other agreement, to such estimate, or Seller may demand assurance of Buyer's performance hereunder adequate to Seller at its sole discretion. Seller's remedies are cumulative and the exercise of any one or more shall not be construed as an election of remedies or waiver of any other remedies available to Seller.

### **4. EXCUSE OF PERFORMANCE**

Delay in shipment or delivery or receipt or other non-performance (specifically excluding the obligation to pay monies due hereunder or complying with Seller's credit terms), in whole or in part, by Seller is excused if performance as agreed is hindered by fire, hurricane, flood, perils of the sea or other acts of God; labor dispute, strike, failure of usual sources of raw material, breakdown or failure of plant or equipment, including transportation facilities; war (whether declared or undeclared), riots, civil commotion, terrorism or sabotage, delay of carriers due to breakdown or adverse weather, embargoes; any applicable foreign or domestic government regulation or order whether or not it later proves to be invalid; import and export restrictions; or other contingency beyond the reasonable control of Seller ("Excuse of Performance"). Seller will promptly give written notice of excusable delays or non-performance to the Buyer and the Order in effect between Seller and the Buyer will be considered to be suspended. If the excusable delay or non-performance continues for an uninterrupted period of sixty (60) days or longer from the date of the written notice the Buyer may, at its option, terminate the Contract on three (3) days written notice to Seller. Delay or non-performance will be excused only as long as the condition causing the delay or non-performance continues. In the event that performance of Seller is delayed or prevented, then Seller has the right, at its option, (a) to cancel the Order to the extent of Seller's non-performance by giving written notice of cancellation to Buyer or (b) to ship remaining quantities in one or more lots after the Excuse of Performance condition has ended (but not beyond sixty (60) days). Cancellation of an Order that has been partially performed does not excuse Buyer from the obligation to pay for Products partially delivered under the Order. Under no circumstances will Seller be obligated to obtain product for delivery hereunder except from its usual and customary source(s) of supply and only on terms it deems reasonable in its sole discretion.

### **5. QUANTITY/QUALITY DETERMINATION**

For bulk liquid product, quantity and quality will be determined by a mutually agreed independent inspector whose decision is to be final and binding, based on shore tanks samples at loading port in accordance with the procedures, product specifications and instructions set forth herein and recognized ASTM methods and adjustments. Each party may have its representative observe all measurements, sample taking and testing. All quantities will be measured or adjusted to a temperature in accordance with recognized ASTM methods and tables, as applicable. For packaged Product, quantity and quality will be as specified in the Order. The mutually agreed inspector's costs are to be shared equally between the parties. The independent inspector's quality determination shall be final and binding on the parties as to the specifications.

### **6. DISCLAIMER OF WARRANTIES AND RELIANCE; BUYER INDEMNIFICATION**

#### **a. Warranties and Reliance**

Seller only represents that the Products conform, within any tolerances stated, to meet the specifications stated in the Order. If no specification is stated, then standard ASTM specifications are to govern.

Except for warranty of title, Seller makes no other representation or warranties, *express or implied*, including, without limitation, warranties of merchantability and fitness for a particular purpose, and Seller expressly disclaims all other representations to the Buyer and any and all other obligations or liabilities on the part of Seller.

No person is authorized to give any other warranties or to assume any other liability on Seller's behalf unless made or assumed in writing by Seller.

**Buyer specifically agrees Buyer is a sophisticated commercial buyer with knowledge of and experience with the Product. Buyer specifically agrees that Buyer has not relied upon any representations by Seller regarding the Product in entering into this Order with Seller. Buyer specifically agrees that Buyer has not relied upon Seller's advice or judgment in entering into this Order. Buyer specifically agrees that Buyer has relied only upon Buyer's own judgment, investigation, and testing of the Product.**

Buyer acknowledges that any or all Products supplied under this Order may be or become or considered a hazardous material under various governmental laws and regulations and that the Buyer or its agents are familiar with any hazards of the Products and its applications and handling of the various modes that the Product may be transported in. If Buyer believes or has reason to believe the information provided to Buyer by Seller is inaccurate or in any way insufficient for any purpose, Buyer will immediately inform Seller of same and provide Seller a reasonable opportunity to supplement or correct the information.

**b. Indemnification**

The Buyer agrees to release, indemnify, defend and hold harmless Seller and its officers, shareholders, employees, agents and successors, from and against any and all claims, demands, suits, attachments, judgments, penalties, fines, liabilities, losses, damages, including incidental and consequential damages, costs and expenses (including reasonable attorneys' fees and costs of court) that may arise in connection with this Order, or result from or relate to the Products (whether in itself or in combination with any other material) or any hazard thereof after title and risk of loss to such Products have passed to the Buyer (including, but not limited to, personal injury (including illness and disease) to or death of any person (including employees of Buyer) or for damage to or destruction of any property). On behalf of Seller, and its agents, servants and/or employees, and in their name, Buyer will handle and/or defend, at its sole expense, any claim or litigation in connection with this Order; provided, however, that Seller reserves the right to handle such litigation with legal counsel of its own choosing at Buyer's expense.

Without limiting the foregoing, the Buyer's agreement to indemnify the Seller includes claims for damages based upon or resulting from the negligence of the Seller, whether the negligence is ordinary, active, passive, joint, concurrent, or sole, but specifically excluding the grossly negligent or willful misconduct of the Seller and the strict liability of the Seller.

Buyer and Seller agree and stipulate that (i) these indemnification provisions are conspicuous and comply with and satisfy the Express Negligence Test and (ii) Buyer and Seller clearly intend to transfer the risk of loss for the Seller's negligence to Buyer.

The Buyer hereby warrants that the Products will not, directly or indirectly, by Buyer or by any third party, be used in any of the **Business Risk Categories** mentioned in:

- Schedule I - **Prohibited and Restricted End Use Policy**
- Schedule II - **Healthcare and Medical Applications Policy**

without prior written approval by Seller for each specific Product and application.

**7. TAXES**

In addition to the contract price, all sales, value added, use and excise taxes and or other taxes and similar charges which Seller is required to pay and which are levied directly upon the sale, transportation, storage, delivery or use of the product delivered hereunder (including any fuel tax for gasoline blendstocks, "superfund" tax and any other environmental tax or like charge assessed or imposed by any governmental authority but excluding franchise tax or tax levied against income of Seller) shall, unless Seller is required to pay such charges pursuant to the delivery terms, be paid by Buyer (or if paid by Seller, reimbursed by Buyer). Seller reserves unto itself all applicable duty drawback allowances.

**8. PAYMENT/CREDIT**

Seller's duty to perform, and Buyer's right to purchase, is at all times subject to the approval, and continuing approval, of Buyer's credit by Seller. The payment terms as stated in the Order by either Letter of Credit or wire transfer per Seller's credit policy, the applicable instruction will be in force:

- Letter of Credit: At least 10 working days prior to the intended date of loading, transfer of title of product or commencement of delivery period, whichever occurs first, Buyer must establish a workable, clean, irrevocable letter of credit that is confirmed and payable at

the counters of a major U.S. bank with terms as required by and acceptable to Seller.

Other terms requested notwithstanding, a documentary letter of credit should provide for draft drawn on negotiating/conforming bank, payment with wire transfer reimbursement upon negotiation, freight payable as per charter party bill of lading, charter party/tanker/blank backed/short form bills of lading acceptable, +/-5% in quantity and value allowed, 30 days for presentation of documents.

- Any non conformance with above provisions would entitle Seller to treat such non conformance as a material breach of contract and to take any steps, including but not limited to cancellation of the shipment/delivery and termination of the Order, necessary to mitigate its risk and damages and recover all losses and damages from the Buyer. Buyer will be fully responsible for all costs and consequences for their actions or lack thereof.

- **Telegraphic (Wire) Transfer:** Wire transfer will be accomplished on the due date in the invoice as instructed by Seller.

- The terms of payment are that the Buyer will make payment of Seller's invoice in full in immediately-available funds into a bank account designated by Seller no later than the due date stated as per the invoice and sales terms in the Order. All payments for Products shipped under an Order shall be in United States of America currency unless otherwise specified in the Order and shall be made without reduction or deduction for offset, adjustment or counterclaim of any kind. Without prejudice to any other remedy or remedies of Seller hereunder or by operation of law, if any amount owed by Buyer is not paid when due, then compound interest to be paid by Buyer to Seller will accrue on the unpaid amount from the due date until paid at one (1%) percentage point per month plus all legal costs.

## **9. SHIPMENT**

The mode and terms of shipment are as set out in the Order and any performance range will always be at Seller's option unless specified otherwise. Buyer will be considered the importer of the Products and is responsible for securing all necessary licenses, consent of any government or local authorities and other required freight, transit and import documentation for acquisition or use of the Products by the Buyer. Failure to do so will not entitle Buyer to withhold or delay payment of the price. Any additional expenses or charges incurred by Seller resulting from such failure will be for Buyer's account. Seller is only responsible for providing a commercial invoice, bill of lading, certificate of quality and quantity, a certificate of origin issued by a chamber of commerce, and, where CIF terms apply, a certificate of insurance. If the delivery terms of the Order requires that the Buyer will charter and/or arrange for the CARRIER (VESSEL/BARGE/TRUCK/RAIL TANK CAR), then the Buyer is, where the delivery term requires, responsible ensuring that the carrier has all the relevant licenses, certificates and permits and is eligible to trade to the places identified in the Order; has the necessary equipment and physical capacity and capability to safely load, carry and discharge the Products; and has tanks with the requisite cleanliness to safely load, carry and discharge the Products. The Buyer is responsible for and shall procure that the carrier complies with the safe handling/loading/unloading/transportation/transfer requirements of the Products under various international conventions/laws/regulations/decrees/directives including but not limited to MARPOL 1973/1978; SOLAS 1974/1978/1981/1983; ISM Code 1994, U.S Port and Tanker Safety Act, the U.S. Maritime Transportation Security Act 2002 (MTSA), U.S Oil Pollution Act of 1990 and the International Convention on Liability and Compensation for Damage in connection with the Carriage of Hazardous and Noxious Substances by Sea, 1996, with all applicable amendments. In the case of shipment or delivery in installments, any delays in or failure of shipment or delivery of one installment shall not be deemed a breach of contract giving rise to a right of the Buyer to cancel the Order or refuse to perform with respect to other installments, if any.

The party obliged to insure the Products shall do so in respect of all risks of carriage associated with the shipment with underwriters or an insurance company of good repute and unless otherwise agree the insurance shall be to the maximum value of the shipment plus 10%. Insurance shall be provided in the agreed currency of the Order. Unless otherwise explicitly agreed in the Order any overage premium under Buyer's insurance policy will be for the account of and paid for by the Buyer.

## **10. MARINE TERMS AND CONDITIONS**

Where applicable the marine terms and conditions will be as per the ruling Charter Party or similar contract of carriage entered into by Seller or the Buyer. If ruling Charter Party is ASBATANKVOY then only Part II clauses 6, 7, 8 and 9 to apply. Demurrage rate shall be as per the Charter Party rate and shall be communicated to the paying party with the vessel nomination.

Demurrage will be paid by the responsible party at the rates specified in the vessel/barge nomination. Demurrage claims must be submitted to the other party within 120 days after the date of discharge. Claims must include an invoice and copies of Statement of Fact and Notice of readiness signed by relevant parties and a copy of demurrage calculations. For FOB sales, demurrage shall not exceed the amount that the charterer of the vessel/barge is liable to pay under the terms of charter party.

Demurrage claims shall be deemed irrevocably accepted if not objected to in writing by the owing party within 30 days of the date of claim and payable immediately. The fact that the owing party has not collected from a third party shall not be an excuse from or defense to a claim for payment by the owed party.

Notices of estimated time of arrival (ETA) and name of vessel/barge/tow will be provided to the receiving or loading party a reasonable time before arrival at port and any changes will be reported promptly. Upon arrival at berth or as close thereto the vessel/barge/tow shall give a notice of readiness to load or discharge only if so fully ready to do so with all port permissions secured.

Seller may refuse to load/unload, transfer, or handle any product under any conditions it deems unsafe for any reason or cause whatsoever, including but not limited to drivers, personnel, equipment, procedures and/or weather conditions. Seller may reject any rail cars, trucks,

transports, pipelines, barges, vessels, containers or storage presented for loading/unloading/transfer which would present an unsafe or potential unsafe situation. Each party's agents and employees will comply with all known safety regulations of the other when such agents or employees are upon the premises of the other in connection with the performance of this agreement.

At unloading points nominated by Buyer, Buyer will be responsible for providing a berth that the tow/barge/vessel may safely proceed to, lie at always afloat and safely depart from with Buyer being responsible for any wharfage/dockage/berth hire/quay or similar dues. To such extent allowed under the Order, if the Buyer nominates a receiving vessel/barge at unloading point instead of a berth to receive the Products the Buyer will be fully responsible for costs/time/consequences/safety/operational effectiveness of such an operation.

If and to the extent, Buyer loads, unloads or ships hazardous materials pursuant to this agreement, Buyer hereby warrants that all hazardous materials will be prepared for shipment, loaded, shipped and unloaded in compliance with all applicable federal, state and local laws, rules and regulations regarding the handling and transportation of hazardous materials and Buyer will indemnify, defend and hold Seller harmless from all liabilities of whatsoever nature to which Seller may become subject as a result of Buyer's failure to comply therewith.

**11. COMPLIANCE WITH LAWS**

Buyer shall comply with all governmental laws, rules and regulations applicable to this transaction, including, without limitation, all such laws, rules and regulations related to exports, imports, sanctions, the environment and safety. Buyer also represents and warrants that Buyer has not, directly or indirectly, in connection with the sale of Products hereunder, made, offered, promised or authorized the payment of anything of value (including any payment for facilitating or expediting any governmental function) (a) to an employee of any government, government-owned or controlled company, political party or international organization, or to a political party, in order to obtain, retain or direct business, to obtain any improper advantage or benefit, or to facilitate or expedite any action on his or her part or by another government employee; or (b) to an agent, representative, intermediary or employee of another company without that company's knowledge and consent, with the intent to influence the recipient's action with respect to his or her company's affairs or business or to gain any improper advantage or benefit to the detriment of his or her company. Buyer further represents and warrants that Buyer will not make, offer, promise or authorize such payment.

**12. RE-EXPORTATION PROHIBITION**

All Products will be shipped to the port of destination specified in the Order and Buyer is prohibited from shipping, delivering, or re-exporting any Products delivered pursuant to the Order to any country other than the country of the port of destination, unless otherwise agreed. Buyer recognizes that U.S. law or regulations may prohibit delivery of product or transshipment to restricted individuals, destinations (E.G., IRAN (IRISL), SYRIA, SUDAN, CUBA, NORTH KOREA, CRIMEA/SEVASTOPOL) or entities and Buyer agrees that it shall make due inquiry and not cause or permit Products sold hereunder to be delivered to any such individual, destination or entity. Seller will not be obligated to any terms or requests including any documentary requests which are prohibited or are penalized under U.S. anti-boycott laws regulations. Buyer shall indemnify, defend and hold the Seller harmless against all costs (including, without limitation, professional fees, penalties and interest), claims, damages, assessments, causes of action, judgments, fines, settlements, penalties and liabilities (joint and several), without regard to amount, to the extent arising out of, caused by or resulting from the indemnifying party's material breach of its obligations under this Section.

**13. ASSIGNMENT**

Neither Seller nor Buyer shall assign the whole or any part of its rights, interests or obligations hereunder directly or indirectly without prior written consent of the other party and any attempt to do so shall be null and void, except that Seller may assign this Order and/or any of its rights or obligations to any affiliated or related company upon giving notice. Nothing in this Order shall be deemed to create any right in any creditor or other person or entity not a party hereto and this Order shall not be construed in any respect to be a contract in whole or in part for the benefit of any third party

**14. TITLE TO AND RISK OF LOSS OF PRODUCTS**

Notwithstanding anything else contained herein or in the sales confirmation or any other related documents, for any export of Products by the legal entity Vinmar International, Ltd. outside of the United States, whereby title would otherwise pass in the United States, title of the Products, regardless of the Incoterms in the sales contract, shall instead pass from Seller to Buyer upon the vessel's passing a point five miles beyond the territorial waters of the United States. For sales not exported from the United States by Vinmar International, Ltd., the title and risk of loss shall pass from Seller to Buyer at the delivery point (in the case of liquid Products, as the Products pass the final flange of the loading or unloading line, as the case may be).

**15. TIMELY NOTICE; LIMITATION OF LIABILITY**

All claims for any cause whatsoever (whether based in contract, warranty, negligence, strict liability, violation of law or tort) shall be deemed waived unless made in writing and received by Seller at its registered address within one hundred twenty (120) days after the later of (i) actual or intended date of transfer of title and risk of loss or (ii) the date Buyer discovered or should have discovered nonconforming product. Failure of Buyer to provide Seller with written notice of any such claim within the applicable time period shall be deemed an absolute and unconditional waiver by Buyer of such claim.

Seller's liability and Buyer's exclusive remedy for any cause of action arising out of or related to this Order is expressly limited at Seller's option to: (a) replacement of nonconforming product as per the agreed delivery term under the Order, or (b) payment of the amount of the sales price allocable to the Products determined to be nonconforming and actually received by Seller.

Seller's total liability arising from this order for any claims of any nature, whether based in contract, tort (including negligence), indemnity, contribution, strict liability or otherwise, will not exceed the purchase price of the portion of the products related to the claim. This constitutes Seller's maximum liability, even if the products have been placed by an end-user or used in other projects. In no event will Seller be liable to Buyer for any damages, lost profits or any incidental, indirect, consequential, special, contingent, exemplary, or punitive damages incurred by Buyer or assessed against Buyer in favor of any downstream purchaser or user.

**16. INCOTERMS**

Where not in conflict with this Order, Incoterms (2010) as amended from time to time shall apply to this Order.

**17. JURISDICTION**

Any lawsuit arising out of a dispute, controversy or other matter in connection with this Order, including matters involving the interpretation, execution, performance, non-performance and/or breach of any obligation under this Order, shall be filed in a Texas State District Court presiding in Harris County, Texas. The parties hereby consent to personal jurisdiction in Harris County, Texas for any suit, controversy or dispute arising out of this Order and the parties agree that Texas state courts sitting in Harris County, Texas shall have sole and exclusive jurisdiction of all suits, controversies or disputes arising out of or in any way connected with the performance, non-performance, interpretation, validity and/or execution of this Order.

**18. APPLICABLE LAW**

The rights and obligations for the transactions between Seller and Buyer under the Order will be governed, construed and enforced by the law of the State of Texas, United States of America, without regard to the doctrine of conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods of Vienna, 11 April 1980, shall not apply to this Order.

**19. ENTIRETY OF AGREEMENT; SEVERABILITY**

This Order constitutes the entire understanding and agreement between Seller and Buyer with respect to the subject matter hereof and supersedes and cancels all previous written and oral agreements, understanding and representations related to the subject matter. Should any clause, sentence, paragraph of this Order be judicially declared to be invalid, unenforceable or void, such decision will not have the effect of invalidating or voiding the remainder of this Order.

**20. CONFIDENTIALITY**

Each party shall keep confidential any information in relation to the Order, the Products or the performance pursuant to this Order, except and insofar as a disclosure will be reasonably required for the performance pursuant to the terms of the Order, or will be required otherwise pursuant to any Court Order, order of any authorities or towards any person pursuant to mandatory law.

**Schedule I – Prohibited and Restricted End Use Policy**

**1.0 Prohibited End Use** – Any party, associated with or conducting business for or with Vinmar in a third party capacity (as an agent, representative, consultant, business partner, supplier or other type of third party), shall not, directly or indirectly engage or participate in, or authorize or assist anyone in shipping, delivering, re-exporting, diverting of any Vinmar product to entities or persons engaged in conducting research, design, support, development, use, construction or any other activity regarding weapons or munitions, missiles or rocket systems, nuclear energy or weapons, chemical or biological weapons or their precursors, delivery systems for such weapons, etc.

**2.0 Restricted applications of Polyolefins** – Polybutene-1 resins for Pipes application : Customer are required to sign specific Sales Agreement, which has specific Terms and Conditions, including the warrant not to supply the pipes and fittings made with PB-1 resins to North America.

**3.0 Restricted applications of Polyolefins** – Baby Car seats: Do not supply Polyolefins or production of Baby car

seats to be sold in North America. For other markets it must be sold directly to customers/ converters and not to resellers or distributors.

**4.0 Prohibited application of Compounded Polyolefins** – Use of Compounded Polyolefins in the following applications is prohibited :-

- All parts of Aeronautical use
- All parts of Train transportation use
- Air bag unit housings
- Seat belt systems and mechanisms
- Brake systems and mechanisms
- Pedals (brake, gas, clutch)
- Steering systems and mechanisms
- All parts with flammability requirements for Building and Constructions
- All parts with flammability requirements for Industrial applications use
- All parts with Medical applications use
- All tobacco related products and applications

## Schedule II – Healthcare and Medical Applications Policy

### 1.0 Business Risk Categories:

#### 1.1 Category A:

- Medical Applications involving permanent implantation into the body.
- Use in a Life-Sustaining Medical Application.
- Use in a United States FDA Class III, Canadian Class IV, European Union Class III devices, or another country's equivalent regulatory classification.
- Use in Life-Sustaining Medical Application.
- Any part or component of the above applications.

##### Non-Exhaustive Examples:

- Replacement heart valves
- Silicone gel-filled breast implants
- Implantable pacemaker
- Hernia/tissue repair mesh
- Parts or replacement joints
- Device placed in natural or surgically-created openings and are intended to remain in the body for a period greater than (30) days.

#### 1.2 Category B:

- Use in United States FDA Class II, Canadian Class II and III, European Union Class II devices, or another country's equivalent regulatory classification.
- Medical Applications where product is in direct contact with a non-solid drug intended for inhalation, injection, intravenous administration, nasal spray or ophthalmic (eye) administration.

##### Non-Exhaustive Examples:

- Blood and IV bags, associated tubing and connectors
- Blood specimen collection devices and accessories
- Hypodermic syringes
- Containers for drugs intended for administration by inhalation, injection, intravenous administration, nasal, or ophthalmic (eye)
- Surgical needles and suture material
- Infusion pumps
- Device placed in natural or surgically-created openings and are intended to remain in the body for a period greater than (30) days.

#### 1.3 Category C:

- Use in United States FDA Class I, European Union Class I, Canadian Class I devices, or another country's equivalent regulatory classification.
- Medical Applications where product is in direct contact with a drug intended for administration either (1) a solid drug or (2) a non-solid drug intended for administration via the digestive tract or topical (skin) applications.

##### Non-Exhaustive Examples:

- Solid pill and capsule containers and closures
- Containers for liquid drugs intended for oral administration (Non-parenteral)

- Tongue depressors
- Bedpans
- Elastic bandages
- Examination Gloves

### 2.0 Definitions:

**2.1 Life-Sustaining Device:** A device which is essential to, or that yields information that is essential, to the restoration or continuation of a bodily function important to the continuation of human life (e.g. a cardiac pacemaker).

**2.2 Medical Applications:** Medical Applications include Medical Devices (as defined below), Pharmaceutical Immediate Packaging (as defined below), and Additional Medical Application Areas (as defined below):

- (a) *Medical Devices:* An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which:
  - (a) 1. is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or other animals, or
  - 2. is intended to affect the structure or function of the body of humans or other animals, and
  - (b) does not achieve its primary intended purposes through chemical action within or on the body, and
  - (c) is not dependent on being metabolized for the achievement of any of its primary intended purposes.
- (b) *Pharmaceutical Immediate packaging:* Packaging in direct contact with pharmaceutical active ingredient and/or dosage form.
- (c) *Additional Medical Application Areas:* The following are considered Medical Applications for the purposes of this Policy:
  - (i) Devices which promote or interfere with human reproduction;
  - (ii) Devices used to disinfect human Medical Devices; and
  - (iii) Film, overwrap and/or product packaging that is part or component of a Medical Device, and is primary packaging, and is in contact with a liquid or gaseous device or a liquid that is in contact with the Medical Device.
- (d) *The following are not considered a part or component of a Medical Device for the purposes of this Policy;*
  - (i) Secondary packaging for Medical Devices used solely for packaging or protecting the primary packaging or Medical Device itself and is discarded upon use.
  - (ii) Primary packaging for solid article Medical Devices used solely for sterile packaging purposes and is discarded upon use.