

## PRODUCT CATEGORIES

IMI will produce and market five major products as follows:

- Syringes and Needles (AD (Immunization Syringes) + RUP (Curative Syringes))
- IV Giving Sets (IVGS)
- IV Solutions (Large Volume Parenteral - LVP)
- Injectables
- Ear, Nose and Eye Drops (ENE)

In addition, IMI will also offer medical consumables and equipment for sale. These will be shipped from our medical store of 14,500m<sup>2</sup>, the largest purpose-built facility of its kind in Africa.



## PRODUCT DESCRIPTION AND KEY FEATURES

### AD Syringes

IMI AD Syringes are designed and manufactured as special syringes that self-destruct after one use, thus preventing dangerous reuse that can result in the transmission of blood-borne pathogens such as Hepatitis B, Hepatitis C and HIV.

The need for AD Syringes has arisen, especially in developing countries, as a counter-measure to combat the unsafe and hugely problematic injection practice of the reuse of the syringe, which has contributed significantly to the spread of blood borne diseases.

AD syringe does not harm the recipient, does not expose the provider to any avoidable risks and does not result in any waste that is dangerous for other people. The AD syringes are versatile and eliminate reuse of syringes for immunization purposes.

IMI Produces both 2 Piece and 3 Piece AD Syringes.

**PRECAUTIONS:** Before use, check the integrity of the sealing of Pack . Do not push the Plunger forward before withdrawing medicine from the vial otherwise Plunger will get locked.

**QUANTITY:** Each Shipping Box contains 12 Sales Boxes of 100syringes per Sales Box.  
Total of 1200 syringes per Shipping Box

### IMI AD Syringe (2 Piece) Specifications

- Available Size : 0.5ml & 0.25ml with Fixed 23G X1” Needle
- Produced according to EN ISO 7886-3:2009
- Auto Disable Feature for one use only.
- Standard quality polypropylene used to ensure clear observation.
- Bold Single graduated scale on the barrel, easy to read
- Needle pull force minimum 34N.

### IMI AD Syringe (2 Piece) Features

- Our Products Comply with WHO-PQS guideline for Immunization Devices E08  
Hypodermic syringe for Fixed dose immunization (Auto Disable Syringes)

## Integrated Medical industries Products Detail

- Capacity with a maximum of 20% excess filling capacity.
- Barrel: Medical grade polypropylene, Nontoxic & compatible with any medications.
- Plunger: Medical grade Polyethylene, Non toxic & compatible with any medication
- No Rubber Gasket
- No reaction with Paraldehyde
- **Prevention from Reuse:** Presence of ring & Lock mechanism which automatically breaks the plunger, either Push or Pull for Reuse attempted.
- Nominal Capacity of the syringes as per EN ISO 7886-3:2009
- Needle have exceptionally sharp lancet point to penetrate tissue smoothly and with minimal pain.
- Needle Point has a bevel angle of  $11^{\circ} \pm 2^{\circ}$
- Individual Piece packed in Medical grade Peel Off Paper and Soft Film
- Final product is sterilized in Fully automatic European EO sterilizer with 90% EO gas.
- All Products Produce under one roof in Clean room Class 10,000

### Quality standards:

- ISO 13485:2003
- CE Mark.
- GMP



### IMI AD Syringe (3 Piece) Specifications

- Available Size : 0.5ml with Fixed 23G X1” Needle
- Produced according to EN ISO 7886-3:2009
- Auto Disable Feature for one use only.
- Standard quality polypropylene used to ensure clear observation and smooth plunger movement
- Bold Single graduated scale on the barrel, easy to read
- Needle pull force minimum 34N.

## Integrated Medical industries Products Detail

### IMI AD Syringe (3 Piece) Features

- Our Products Comply with WHO-PQS guideline for Immunization Devices E08 Hypodermic syringe for fixed dose immunization (Auto Disable Syringes).
- Capacity with a maximum of 20% excess filling capacity.
- Barrel & Plunger: Medical grade polypropylene, Nontoxic & compatible with any medications.
- Gasket: Highly inert material in line with global standards
- No reaction with Paraldehyde
- **Prevention from Reuse:** Presence of ring & Lock mechanism which automatically breaks the plunger, Pull for Reuse attempted.
- Nominal Capacity of the syringes as per EN ISO 7886-3:2009.
- Needle have exceptionally sharp lancet point to penetrate tissue smoothly and with minimal pain.
- Needle Point has a bevel angle of  $11^{\circ} \pm 2^{\circ}$
- Individual Piece packed in Medical grade Peel Off Paper and Soft Film
- Final product is sterilized in fully automatic European EO sterilizer with 90% EO gas.
- All Products Produce under one roof in Clean room Class 10,000

### Quality standards:

- ISO 13485:2003
- CE Mark.
- GMP

### Reuse Prevention Syringes (RUP Syringes)

IMI RUP Syringes are designed and manufactured as special syringes that self-destruct after one use, thus preventing dangerous reuse that can result in the transmission of blood-borne pathogens such as Hepatitis B, Hepatitis C and HIV.

RUP syringe does not harm the recipient, does not expose the provider to any avoidable risks and does not result in any waste that is dangerous for other people. The RUP syringes are versatile and eliminate reuse of syringes for curative purposes.

IMI Produces 2 piece and 3 piece RUP syringes

**PRECAUTIONS:** Before use, check the integrity of the sealing of Pack. Do not push the Plunger forward before withdrawing medicine from the vial otherwise Plunger will get locked.

## Integrated Medical industries Products Detail

**QUANTITY:** Each Shipping Box contains 12 Sales Boxes of 100syringes per Sales Box.  
Total of 1200 syringes per Shipping Box

**COST:** Contact sales team

### IMI RUP Syringes (2 Piece) Specifications

- Available Sizes: 2ml, 5ml &10ml
- Produced according to EN ISO 7886-4:2009
- Nominal Capacity with a maximum of 20% excess filling capacity.
- Reuse Prevention Feature for one use only.
- Standard quality polypropylene used to ensure clear observation.
- Bold graduated scale on the barrel, easy to read

### IMI RUP Syringe (2 Piece) Features

- Our Products Comply with WHO-PQS guideline for Therapeutic Device E013 Hypodermic Syringes with Reuse Prevention Feature (RUP Syringes)
- Barrel: Medical grade polypropylene, Nontoxic & compatible with any medications.
- Plunger: Medical grade Polyethylene, Non toxic & compatible with any medication
- Nominal Capacity of the syringes as per EN ISO 7886-4:2009
- Dead space maintained as per EN ISO 7886-4:2009
- **Prevention from Reuse:** Presence of ring & Lock mechanism which automatically breaks the plunger, either Push or Pull for Reuse attempted.
- No Rubber Gasket
- No reaction with Paraldehyde
- Needle have ultra-thin wall permitting rapid and efficient drug delivery
- Final product is sterilized in Fully Automatic European EO sterilizer with 90% EO gas.
- Nozzle Lumen as per EN ISO 7886-4: 2009

## Integrated Medical industries Products Detail

- Needle Point has a bevel angle of  $11^{\circ} \pm 2^{\circ}$
- individual Piece packed in Medical grade Peel Off Paper and Soft Film
- All Products Produce under one roof in Clean room Class 10,000

### **Quality standards:**

- ISO 13485:2003
- CE-Mark
- GMP

### **IMI RUP Syringes (3Piece) Specifications**

- Available Sizes: 2ml & 5ml
- Produced according to EN ISO 7886-4:2009
- Nominal Capacity with a maximum of 20% excess filling capacity.
- Reuse Prevention Feature for one use only.
- Standard quality polypropylene used to ensure clear observation and smooth plunger movement
- Bold graduated scale on the barrel, easy to read

### **IMI RUP Syringe (3 Piece) Features**

- Our Products Comply with WHO-PQS guideline for Therapeutic Device E013 Hypodermic Syringes with Reuse Prevention Feature (RUP Syringes)
- Barrel: Medical grade polypropylene, Nontoxic & compatible with any medications.
- Plunger: Medical grade Polypropylene, Non toxic.
- Gasket: Highly inert material in line with global standards.
- **Prevention from Reuse:** Presence of ring & Lock mechanism which automatically breaks the plunger, Pull for Reuse attempted
- Nominal Capacity of the syringes as per EN ISO 7886-4:2009
- Dead space maintained as per EN ISO 7886-4:2009

## Integrated Medical industries Products Detail

- Nozzle Lumen as per EN ISO7886-4: 2009
- Needle Point has a bevel angle of  $11^{\circ} \pm 2^{\circ}$
- Needle have ultra-thin wall permitting rapid and efficient drug delivery
- Individual Piece packed in Medical grade Peel Off Paper and Soft Film
- Final product is sterilized in Fully Automatic European EO sterilizer with 90% EO gas.
- All Products Produce under one roof in Clean room Class 10,000

### **Quality standards:**

- ISO 13485:2003
- CE Mark.
- GMP

## Single use Syringes

Hypodermic single use syringes are used with Hypodermic Needle to inject fluid into body tissues, or to remove from the body. Single-use syringes effectively reduce the risk of cross-contamination.

Single use syringe does not harm the recipient, does not expose the provider to any avoidable risks and does not result in any waste that is dangerous for other people. The Syringes are versatile and use in Laboratory and general curative purpose.

### **IMI Single use Syringe Features**

- Barrel: Medical grade polypropylene, Nontoxic & compatible with any medications.
- Plunger: Medical grade Polyethylene, Non toxic & compatible with any medication
- Nominal Capacity of the syringes as per EN ISO 7886-1
- Dead space maintained as per EN ISO 7886-1
- No Rubber Gasket
- No reaction with Paraldehyde
- Needle have imported ultra-thin wall permitting rapid and efficient drug delivery
- Final product is sterilized in Fully Automatic European EO sterilizer with 90% EO gas.

## Integrated Medical industries Products Detail

- Nozzle Lumen as per EN ISO 7886-1
- Individual Piece packed in Medical grade Peel Off Paper and Soft Film
- All Product Produce under Clean room Class 10,000

### Quality standards:

- ISO 13485:2003
- CE-Mark
- GMP

### IMI Single use Syringes Specifications

- Available Sizes: 2ml, 5ml &10ml
- Produced according to ISO 7886-1
- Nominal Capacity with a maximum of 20% excess filling capacity.
- Standard quality polypropylene used to ensure clear observation.
- Bold graduated scale on the barrel, easy to read



### Hypodermic (Single use) Needles

The hypodermic needle is a device used with AD/RUP syringes by medical professionals to transfer liquids into or out of the body. It is made up of a hollow tube. The hypodermic needle is produced from steel, which is first heated until it is molten and then drawn through a die designed to meet the size requirements of the needle. As it moves along the production line, the steel is further formed and rolled into a continuous hollow wire. The wire is appropriately cut to form the needle.

Other plastic components like hub, cap on the needle are produced through molding. An advanced automatic needle assembly machine having almost no human touch performs assembly of steel parts and other components.

### IMI Hypodermic Single use Needles Specifications

- Available Sizes: 21G, 22G & 23Gml
- Produced according to ISO 7864
- Single use only.
- Standard quality polypropylene used to ensure clear observation.



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### IMI Hypodermic Single use Needles Features

IMI's hypodermic needles have the following special features and advantages:

- Best-quality needle tube
- Sharp edge for smooth penetration
- Corrosion free needle tube
- Triple bevel angle for almost no pain
- Color coding as per ISO standard
- Comply with ISO 7864 standard for Hypodermic Needle.

### IVGS (Intravenous-Giving Sets)

The IVGS is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device includes a needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an IV set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an IV bag or other infusion fluid container.

The products of this range are generally used in delivering measured and regulated fluids to patients. IV Giving sets are made up of a cylindrical drip chamber with / without vent provided with a filter to prevent passage of clot to patient.

#### Features of IVGS

The following are the special features and comparative advantages of the IVG Sets manufactured by IMI:

- Clear, transparent and flexible long drip chamber made from medical grade plastic resin
- Molding and assembly in a clean room environment to ensure pyrogen-free status
- Incorporated air-filter component to prevent contaminated air.
- Incorporated particle filter component to prevent particle contamination
- DEHP-free PVC material for the tubing component
- Functional drip-control mechanism for smooth control of fluid
- Packaging in medical-grade blister paper to permit sterilization
- Sterilization with ethylene-oxide gas

### **Blood-Transfusion Sets (BTS)**

These products are typically used in general surgery to minimize surgery time. Blood transfusion sets are used to deliver measured and regulated blood to patients. A BTS is made up of a cylindrical drip chamber with / without vent provided with filter to prevent passage of clots to patients.

#### **Features of BTS**

The following are the special features of BTS manufactured by IMI:

- Clear, transparent and flexible drip chamber made from Medical grade plastic resin
- Molding and assembly in a clean room environment to ensure pyrogen-free status
- 6% taper for compatibility with international products.
- Incorporated air-filter component to prevent contaminated air.
- Incorporated particle filter component to prevent particle from air.
- DEHP-free PVC material for the tubing component.
- Functional drip-control mechanism for smooth control of fluid.
- Packaging in medical-grade blister paper to permit sterilization.
- Sterilization with ethylene-oxide gas.

### **Intravenous (IV) Solutions (Large Volume Parenterals (LVP))**

Intravenous (infusion) therapy supports the restoration and stabilization of homeostasis, which is described as the “physiological equilibrium” of the human organism. Infusion therapy as a basic tool of modern medical care enables physicians to restore and stabilize homeostatic stress quickly and completely. There are four main areas of application of highly specialized intravenous infusion solutions. These are:

- Treatment of disturbed water and electrolyte metabolism, especially in severe cases
- Therapy of acid-base imbalances
- Volume substitution and volume replacement in surgery of an accident victim suffering blood loss and Parenteral nutrition for severely ill and post-operative patients.

LVPs are sterilized pyrogen-free solutions used as a first line of treatment for patients with high fevers and dehydration. LVPs are also used in combating the effects of AIDS-related diseases and complications of childbirth. The IV fluids reduce dehydration, enable patients to improve blood circulation and help in maintaining body weight. They contain various electrolytes such as sodium, potassium, calcium, chloride, and dextrose among others, to enhance body immunity.

The LVP consists of either sterile water or low concentrated solutions of saline, dextrose, carbohydrates, electrolytes, lipids, vitamins, proteins, etc. in pure sterile and pyrogen-free

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water intended for intravenous administration to patients who require acute maintenance therapy and also Total Parenteral Nutrition (TPN) because of inability to swallow or digest.

LVP solutions are either administrated alone, or as a vehicle for delivering into the human body drugs and medications that are mixed in for a wide variety of therapies. Among such formulations are: antibiotics, anesthetics, anti-inflammatory or chemotherapy for cancer treatment, and so on.

IMI's LVPs will be produced using the Rommelag GMP-approved advance Blow-Fill- seal (BFS) technology, which will minimize the risk of contamination during the production process. BFS machines are contained within complete HEPA ceiling Class 1,000 "clean rooms". The LVPs are produced under fully automatic close production cycle, combining extrusion, filling and sealing of container, all before leaving the inside of the machine.

### Features of LVP

The following are additional features/ advantages of IMI's produced LVPs:

- Low particle contamination in contrast to glass bottles and PVC bags
- DEHP (Harmful Plasticizer)-free containers
- Lower water evaporation in contrast to PVC bags
- Low weight
- Unbreakable
- Environmentally harmless: IMI produced infusion containers do not contain any plasticizers and are recyclable. Even when incinerated the only by-products are CO<sup>2</sup> and H<sub>2</sub>O
- No venting necessary.
- Good handling, stable.
- Polyethylene is suitable for nearly all solutions
- Assembled with Eurocap, which prevents the risk of considerable particle contamination and ease of addition of other medicines.

## Injectables

IMI Injectables is highly purified solution used as a vehicle for injectable preparations that will be subsequently sterilized. Total solid contents cannot be more than 10 parts per million. It will have a pH of 5.0 to 7.0. The Injectables will be prepared by distillation process, which will meet the standards of USP pyrogen test and will not contain any added substances.

### Features of Injectables

The following are the features/ advantages of IMI's Injectables:

- Low particle contamination in contrast to glass bottles and PVC bags.
- DEHP(Harmful Plasticizer) - free container
- Unbreakable
- Free-standing.

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- Even open containers that fall over do not run out
- Open without filing that means without splinters and the danger of injury
- Simple, problem-free disposal
- Polyethylene is suitable for nearly all solutions.

### Ear Nose and Eye Drops (ENE)

Ear Nose and Eye Drops (ophthalmic preparations) are sterile, liquid preparations intended for administration to the ear, nose and eyeball and/or to the conjunctiva.

**Eye drops** are saline-containing drops using the ocular route to administer medication. Depending on the condition being treated, they may contain steroids, antihistamines, sympathomimetics, beta-receptor blockers, parasympathomimetics, parasympatholytics, prostaglandins, non-steroidal anti-inflammatory drugs (NSAIDs) or topical anesthetics. The drops are commonly used for symptoms such as eye irritation, redness, dryness and itching of the eye caused by an allergy, head cold, or a related upper- respiratory problem. Eye drops sometimes do not have medications in them and are only lubricating and tear-replacing solutions.

**Ear drops** are a sterile solution or suspension of medicine. They are administered into the ear to produce a local effect directly on the outer ear canal to prevent infections. Bacterial infections are sometimes treated with antibiotics.

**Nose drops** are medicines or formulas that are ingested through the nose. The drops may be formed of a saline solution or could have a medication as an active ingredient. The drops are commonly used for symptoms such as nasal congestion caused by an allergy, head cold, or a related upper-respiratory problem.

### Features

Following are the features/advantages of IMI's Ear Nose and Eye drops:

- Low particle contamination in contrast to glass bottles and PVC bags.
- DEHP- free (Harmful Plasticizer) container
- Unbreakable
- Free-standing
- Even open containers that fall over do not run out
- Open without filing, that means without splinters and the danger of injury
- Simple, problem-free disposal

### **Eurocap**

Eurocap is a safety cap welded onto the bottleneck of the LVP bottle. It is made of Thermo Plastic elastomer (TPE) that is housed in a PE enclosure (cap). TPE works as an elastic re-sealant, and it completely and fully reseals, even after a spike/needle has been inserted and removed through it. The conventional LVP Bottle-pack infusion with Otsuka/nipple head does not reseal, so there is a great risk of contamination through the opening that is created by the insertion and removal of a spike or needle. The LVP with the nipple head is also not easy for the health workers to use, due to hardness of the plastic material. In some instances, it becomes very difficult to insert spike or administer medication.

### **Features of Eurocap**

The following are the advantages of Euro caps:

- Easy to administer medicine during infusion
- It prevents outside contamination due to its nature of being re-sealable
- It prevents needle stick injury since it is made of a soft material
- It prevents leakage from neck of the bottle



## **DEHP-free Medical Tubing (Component of IVGS /BTS)**

IMI shall only use PVC that is DEHP-free to manufacture the tube which is used in IVGS and BTS to connect the infusion solution/blood bag to the patient via a spike and needle catheter. DEHP Di (-ethylhexyl 1) phthalate is a plastizer used to soften the PVC. However, there have been many reports and studies that confirm that the use of DEHP is harmful to humans, as follows:

- It impacts on direct patient health and safety
- It alters levels of many enzymes, growth factors, immune system, sexual differentiation and hormones
- It is potentially carcinogenic.

The American FDA/CDRH have reported that DEHP exposure could adversely affect reproductive development in infants less than 1 year because of their greater susceptibility and uncertainties regarding exposure. Some reports suggest it may create cancer after certain amount of consumption. Considering the above complications, as well as the US FDA advice, IMI has made the strategic health, safety, environment, and strategic business decision to use only DEHP-free PVC for the manufacture of the tube for IVGS and BTS.