



GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
OUSHAD BHABAN, MOHAKHALI
DHAKA-1212, BANGLADESH
www.dgda.gov.bd



**CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP)
FOR PHARMACEUTICAL (PRODUCT(S))**

This certificate conforms to the format recommended by the World Health Organization (WHO)

Certificate Number: DGDA/6-229/2019/ 14732

Date: 08 AUG 2023

It is hereby certified that **M/s. JMI Hospital Requisite Manufacturing Ltd.**, a drug (Components of Medical Devices, Medical Devices, Surgical Products & Medical Equipment's) manufacturing, exporting and marketing organization, has been given license to manufacture and sell its products freely in the People's Republic of Bangladesh, as lawfully required and granted in pursuance of **The Drugs Acts 1940 (XXIII of 1940) & The Drugs (Control) Ordinance, 1982, and its Amendment Act 2006.**

On the basis of the inspection carried out on 30-06-2022 & 06-01-2023, we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the capacity forms, categories and activities listed in Table -1.

1. Name and Address of site : **JMI Hospital Requisite Manufacturing Ltd.**,
Vitikandi, Gazaria-1510, Munshiganj, Bangladesh
2. Manufacturer's license Number : Biological-298
and Date of issue : Date: 17-02-2014
3. Table-1 :

<i>Form(s) of Product(s)</i>	<i>Category (ies)</i>	<i>Activity (ies)</i>
Scalp Vein Set / Butterfly needle (Non- Sterile)	Size: 19G, 20G, 21G, 22G, 23G, 24G, 25G, 27G	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Product Analysis & Release, Storage and Delivery.
Bulk Needle / Hypodermic Needle (Non-Sterile)	Size: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Product Analysis & Release, Storage and Delivery.
Components of I.V. Infusion Set	Assembled Air Vent/Non Vent Drip Chamber, Slider with Roller/ Flow Regulator, Fluid Filter/ Precision Filter, Y- Injection Port, Luer Slip/Lock Connector.	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Product Analysis & Release, Storage and Delivery.
Cannula (Non-sterile)	Size: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	Quality Control of Incoming Materials, In-process Control, Manufacturing, Packaging, Product Analysis & Release, Storage and Delivery.

Components of I. V. Cannula	Intravenous Cannula: 14G, 16G, 18G, 20G, 22G, 24G, 26G	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Product Analysis & Release, Storage and Delivery.
Components of Blood Transfusion Set	Assembled Air Vent Blood Drip Chamber (B.T.S) (Blood Filter, Fabric filter) Slider with Roller,	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Product Analysis & Release, Storage and Delivery.
Components of Urine Drainage Bag /Drain Bag	Urine Drainage Bag/Drain Bag	Quality Control of Incoming Materials, In-process Control, Manufacturing, Printing, Assembling, Packaging, Product Analysis & Release, Storage and Delivery.
JMI Latex Examination Gloves (Powdered)	Latex Examination Gloves (Small, Medium, Large)	Quality Control of Incoming Materials, In-process Control, Packaging, Product Analysis & Release, Storage and Delivery.
JMI Latex Surgical Gloves (Powdered)	Sterile Latex Surgical Gloves (6.0,6.5,7.0,7.5, 8.0)	Quality Control of Incoming Materials, In-process Control, Packaging Sterilizing, Product Analysis & Release, Storage and Delivery.
JMI Buret Set	Volumetric Infusion Set	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Delivery.
JMI Alcohol Prep Pad	Alcohol Prep Pad/ Alcohol Swab	Quality Control of Incoming Materials, In-process Control, Packaging, Product Analysis & Release, Storage and Delivery.
J-LENE (Monofilament, Polypropylene blue, Synthetic Non-absorbable Surgical Suture USP)	Needle :Stainless steel (Curvature: 1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, J shape, Compound curved, 1/2 curved, Straight) Thread : Polypropylene, non-absorbable, synthetic.USP Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0,0,1, 2, 3, 4, 5)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Delivery.

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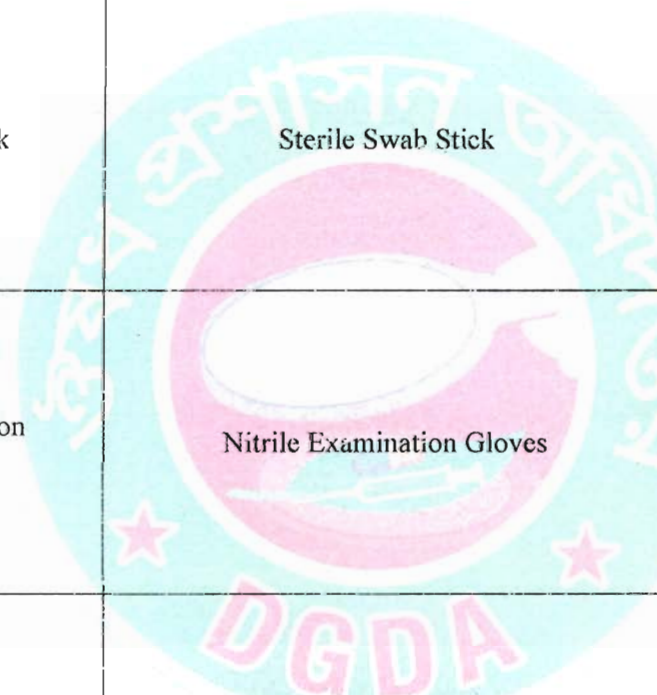
<p>J-SILK (Braided Silk Black, Natural non-absorbable Surgical Suture USP)</p>	<p>Needle :Stainless steel (Curvature: 1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, J shape, Compound curved, 1/2 curved, Straight) Thread: Silk, non-absorbable, natural. USP Size: 9-0, 8-0,7-0, 6-0, 5-0, 4-0, 3-0, 2-0,0,1, 2, 3, 4)</p>	<p>Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Delivery.</p>
<p>J-CRYL (Braided coated Polyglactin 910, synthetic absorbable, surgical suture USP)</p>	<p>Needle: Stainless steel (Curvature: 1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, J shape, Compound curved, 1/2 curved, Straight) Thread: Polyglactin 910, absorbable, synthetic, USP size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0,0,1, 2, 3, 4, 5)</p>	<p>Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery.</p>
<p>J-GUT Chromic (Catgut Chromic, natural, absorbable, surgical suture USP)</p>	<p>Needle: Stainless steel (Curvature: 1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, J shape, Compound curved, 1/2 curved, Straight) Thread: Catgut Chromic, absorbable, natural (USP Size: 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0,0,1, 2, 3, 4)</p>	<p>Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery</p>
<p>J-GUT Plain (Catgut Plain, natural, absorbable surgical suture USP)</p>	<p>Needle: Stainless steel (Curvature: 1/2 circle, 3/8 circle, 1/4 circle, 5/8 circle, J shape, Compound curved, 1/2 curved, Straight) Thread: Catgut Plain, absorbable, natural (USP Size: 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0,0,1, 2, 3, 4)</p>	<p>Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery</p>
<p>JMI Butterfly Needle for Blood Collection</p>	<p>Blood Collection Needle (21G, 22G, 23G)</p>	<p>Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery</p>
<p>JMI Sterile Disposable Scalpel</p>	<p>Sterile Disposable Scalpel (Size: 10, 10A, 11, 12, 15, 20, 21, 22, 23, 24)</p>	<p>Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery</p>

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JMI Sononed (Atraumatic Needle for Peripheral Nerve Blocks)	Sononed (Atraumatic Needle for Peripheral Nerve Blocks) Size: 20G/21G/22Gx25mm 20G/21G/22Gx32mm 20G/21G/22Gx60mm 20G/21G/22Gx100mm	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery
JMI Oxygen Mask with tubing	Oxygen Mask with Tubing (S,M ,L, XL)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery
JMI Nasal Oxygen Cannula	Nasal Oxygen Cannula (Neonatal, Infant, Child, Adult)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery
JMI Nebulizer Mask with Chamber & Tubing	Nebulizer Mask with Chamber & Tubing (S,M ,L, XL)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Packaging, Sterilizing, Product Analysis & Release, Storage and Delivery.
JMI Guedel Airway (Oropharyngeal Airway)	Guedel Airway / Oropharyngeal Airway (000, 00, 0, 1, 2, 3, 4, 5, 6/ 40,50,60,70,80,90,100,! 10,120)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Packaging, Sterilizing, Product Analysis & Release, Storage and Delivery.
Shin-ject insulin syringe 1ml	Insulin Syringe 1 ml (U- 40) Insulin Syringe 1 ml (U- 100)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery

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JMI Autoclave/ Steam Sterilizer	Autoclave/ Steam Sterilizer (5L,10L,30L,50L,75L,100L)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery
JMI Sterile Latex Surgical Gloves (Powdered Free)	Latex Surgical Gloves (Powdered Free) (6.0,6.5,7.0,7.5)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery
JMI Sterile Swab Stick	Sterile Swab Stick	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery
JMI Nitrile Examination Gloves	Nitrile Examination Gloves	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery
J-NON	Polydioxanone Suture (Monofilament, Synthetic, Absorbable surgical suture USP)	Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packaging, Sterilizing, Product Analysis & Release, Storage and Product Delivery



Handwritten signature or initials.

The responsibility for the quality of the individual batches of the pharmaceutical/ Medical devices products manufactured through this process lies with the manufacturer.

The manufacturing plant in which the pharmaceutical products (Components of Medical Devices, Medical Devices, Surgical Products and Medical Equipment's) are produced is subject to inspection at suitable intervals.

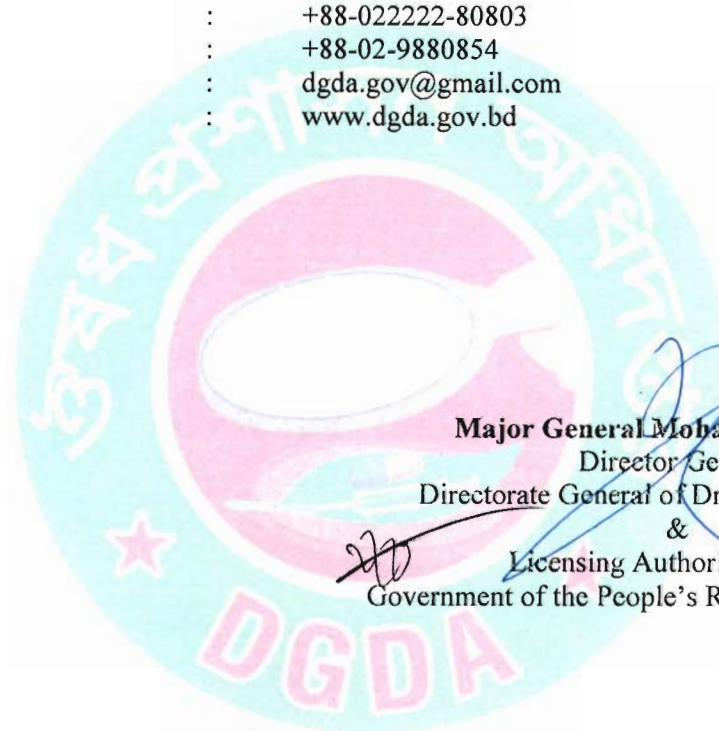
The manufacturer conforms to the requirements for good practices in the manufacture and quality control (GMP) of drugs, as required under law in this country, as well as recommended by the World Health Organization (WHO) in respect of pharmaceutical products to be manufactured, sold or distributed within the country of origin or to be exported.

This Certificate will remain valid for a period of 2 (Two) years from the date of issue.

It becomes invalid if the activities and/or categories certified hereby are changed or if the site is no longer considered to be in compliance with GMP.

Name of Authorized Person : **Major General Mohammad Yousuf**
Address of the certifying Authority : **Directorate General of Drug Administration**
Mohakhali, Dhaka-1212
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Email : dgda.gov@gmail.com
Web : www.dgda.gov.bd

Stamp and date:



Major General Mohammad Yousuf
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

08 AUG 2023