

Handbook on Medical and Surgical Disposable Products (Blood Bags, Plastic Gloves, I.V. Cannula, Infusion Set, Gowns, Masks, Catheter, Cotton and Bandage, Surgical Wear, Syringes)

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Handbook on Medical and Surgical Disposable Products
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Medical and surgical device manufacturers worldwide produce a multitude of items that are intended for one use only. The primary reason is infection control; when an item is used only once it cannot transmit infectious agents to subsequent patients. Like medicines and other health technologies, they are essential for patient care – at the bedside, at the rural health clinic or at the large, specialized hospital. The demand of these goods is not only because of their “one time use” property but also due to the hygienic methods adopted to produce them. From manufacturing to Marking, production of disposable goods is stacked with numerous standards and regulations. This book includes the basic manufacturing method and labeling requirements, required for the bulk production of such life saving devices. General medical disposables that are being in demand in domestic as well as in international market includes: medical gloves, syringes, gowns, catheters, blood transfusion units and so on.

The information provided is not only confined to the different methods involved in the manufacturing of medical disposables but also describes the raw material used and other information related to product, which are necessary for the manufacturers knowledge. The details given will be very good for an individual/entrepreneur who is willing to invest in the field of medical disposables.

The main demand of medical disposables are, nowadays not limited to the super specialty hospitals but is also continuously increasing in rural hospitals and clinics. The work provides an idea to reader about the final product, hygiene, safety, packaging, uses, manufacturers and suppliers of the machinery, raw material involved in the processes etc.

The book covers various aspects concerned with the disposable medical devices and presents an overview of the processes involved with their machineries and specifications. The work provides the complete details of the suppliers and manufacturers with machinery photographs for better understanding of the reader.

1. INTRODUCTION

Design, Prototyping and Product Development

Importance of Testing

2. CE MARKING

Medical Devices

Active Implantable Medical Devices

In Vitro Diagnostic Medical Devices

Competent Authority

Notified Body

Guide to CE Marking

Reproduce the CE Marking

Steps for Class I Medical Devices Compliance

Class I Medical Devices: Conformity Assessment Routes

3. CLEANROOM TECHNOLOGY

Introduction

Humans in Cleanrooms

Contamination Process

Sources of Contamination

1. Facilities

2. People

3. Tool Generated

4. Fluids

5. Product Generated

Key Elements of Contamination Control

List of Some of Equipment and Supplies Needed to Clean the Cleanroom

Classification of Cleanrooms

Conventionally Ventilated Cleanrooms

Unidirectional Airflow Cleanrooms

Mixed Flow Cleanrooms

Isolator or Minienvironment

International Standards

Cleanroom Garment System

Testing of Cleanroom Clothing

Effect of the Garment Design on Dispersion

Comparison of Clothing made from Different Fabrics

Regulations

General Cleanroom Regulations

Personal Actions Typically Prohibited in Cleanrooms

Layout of Cleanroom Suite

Cleaning Methods and the Physics of Cleaning Surfaces

How Should a Cleanroom be cleaned?

Cleaning Methods with Respect to Area Type

Choice of Materials

Test Methods

Furniture

Electrical

Cleanroom Equipments

4. MEDICAL DEVICE PACKAGING

Packaging

Packaging Design Controls

User Preference

Packaging Materials

Package Validation

Procurement, Acceptance and Storage

Packaging Process

Exhibits

Product Specification: Pouch

Header Bag (Specification Form)

Mandatory Label Information

Product Identity Declaration

Language

Location

Net Quantity Declaration

Manner of Declaring

Different Stages of Packaging

Primary Packaging

Chevron Peel Pouch

Corner Peel Pouch

Chevron Peel Pouch

Squared Sealed (No-peel, Tear) Pouch

Standard Method of Dimensioning Pouches

Standard Tray with Undercuts

Tray with Molded Lid

Tray with Heat Sealed Lid

Dual Sterile Barrier – Inner & Outer Tray

Die Cut Backer Cards

Secondary Packaging

Folding Cartons

Corrugated Shipping Containers

Packaging Standards

ISO

ISO-11607

Packaging for Terminally Sterilized Medical Devices

ASTM

ASTM D Standards

ASTM International Standards Fall into Six Categories

ASTM F Standards

ASTM-F1929

Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

Current Good Manufacturing Guidelines for Finished Pharmaceutical Goods

Materials Examination and Usage Criteria

Labeling Issuance

Packaging and Labeling Operations

Drug Product Inspection

Expiration Dating

5. DISPOSABLE BLOOD BAGS

Introduction

Flexible PVC Blood Bags

Uses of Blood Bags

Properties of Disposable Blood Bags

Raw Material

Quality of the Raw Materials

1. Translucency so can Check it Full, and See Layers in Centrifuged Bags
2. Flexibility (Low Bending Stiffness) so can Process by Squeezing the Bag
3. Heat Resistance, so can Steam Sterilize Prior to Use
4. Materials Property-Melting Temperature
5. Must Not Burst in the Centrifuge, or Tear on Handling
6. Permeable to Oxygen, but not too Permeable to Water
7. Moderate Cost
8. Processing and Welding
9. PVC Plasticized Blood Bag sizes: 350 ml & 450 ml

Manufacturing Process

Flow Sheet Diagram

Bag Making

Tube Making

Blood Bag Forming Machine

Suppliers of Plant & Machinery

Raw Materials Addresses

6. DISPOSABLE PLASTIC GLOVES

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Properties

Uses

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Raw Material

Basic Plant and Machineries Required

Steps

1. Washing
2. Coagulation
3. Application
4. Dripping
5. Gelling
6. Leaching
7. Beading
8. Slurry
9. Stripping
10. Testing
11. Packaging

Process Flow Diagram

Glove Manufacturing Machines

PE Glove Machine

Disposable Glove Making Machine

Non-Woven Glove Sewing Machine

Non woven Glove Making Machine

Suppliers of Raw Material

Suppliers of Plant Machineries

7. DISPOSABLE MASKS

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Manufacturing Process of Disposable Surgical Masks
Sterilization
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Machinery Images for Masks
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Surgical Mask Sewing Machine
Mask Blank Machine
Plant & Machinery Suppliers

8. DISPOSABLE SURGICAL CATHETERS

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Uses & Applications
Common Features of Central Venous Catheter (CVC)
Manufacturing Process of Catheters
Process Flow Diagram of Catheter
Catheter Production Equipments
Plant & Machinery Suppliers
Suppliers of Raw Materials

9. DISPOSABLE SURGICAL WEAR

(Surgical Gowns, Bed sheets, Pillow cover, Caps)

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Disposable Pillow Cover
General Construction for Disposable Gowns
Closures
Sizing Analysis of Disposable Gowns
Standards
The General Requirements for Manufacturers, Processors and Products – EN 13795-1
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Face Masks
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Dust Mask
Advantages
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Description of Patient Gown
Description of Surgeon Suits
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Non-Woven Gown making Machine
Disposable Surgical Cap Making Machine
Process Flow Diagram
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Disposable Gown
Disposable Surgeon Gown
Disposable Coverall
Disposable Surgical Cap
Disposable Bouffant Cap
Disposable Mob Cap
Disposable Surgical Bed Sheets
Plant & Machinery Suppliers
Raw Materials Suppliers

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Necessity of Disposable Syringes
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Piston
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Polypropylene
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Synthetic Polymeric Material
Silicone Oil
Leakage Test
Sterility
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2nd Stage of Production
3rd Stage of Process
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Disposable Syringe Packaging Machine
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Medium for Anaerobic Organism
Medium for Aerobic Organism
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Suppliers of Raw Material

11. I.V. (INTRA-VENOUS) CANNULA

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Peripherally Inserted Central Catheter
Central Venous Catheter
Uses and Application
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Plastic Injection Moulding

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4. Unloading/Demoulding

The Blow Moulding Process

- A. Injection Blow Moulding
- B. Extrusion Blow Moulding
- C. Stretch Blow Moulding

The Compression Moulding Process

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Manufacturing Process Assembly Line

Wings

Needle

Tubing

Silicon Valve

Safe Blood Stopper

Packing

Catheter Material as per USP standards Class VI

Process Description of the Assembly Line

Automatic Cup Forming Machine

Semi Automatic Body Assembly/Wing Assembly Machine

Semi Automatic Tip Forming Machine

Automatic Silicon Tube Cutting Machine

Automatic Needle Assembly Machine

Automatic Luer Lock & Flash Back Chamber Assembly Machine

Automatic Catheter Cutting Machine

Automatic Blister Packing Machine

Ethylene Oxide (ETO) Sterilization Process

Pre-Conditioning Stage

Sterilizer Stage

Degasser Stage

Process Flow Diagram

Machinery for IV Cannula Production Line

Automatic Needle Assembly Machine

Automatic Luer Lock & Flash Back Chamber Assembly Machine

Cannula Assembly Machine

Body Assembly Machine

Tip Forming Machine

Cup Forming Machine

Catheter Cutting Machine

Suppliers of Raw Material

12. INFUSION SET & BLOOD TRANSFUSION SET

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After the Blood Transfusion
Blood Transfusion Process Protocol
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The Blow Moulding Process
1. Injection Blow Moulding
2. Extrusion Blow Moulding
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Stretch Blow Moulding
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Suppliers of Raw Material

13. SURGICAL COTTON & BANDAGES

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2. Boiling
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8. Packing

Flow Sheet for the Manufacture of Surgical Cotton

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2. Drawing
3. Combing
4. Spinning
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6. Washing and Bleaching
7. Starching & Natural Drying
8. Cutting the Bandages Cloth into Bandage
9. Packing

Flow Sheet for the Manufacture of Surgical Bandage

Machinery Images & Specifications

1. Surgical Cotton Machinery
2. Bandages Making Machines

Plant & Machinery Suppliers

About NIIR

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Our Detailed Project report aims at providing all the critical data required by any entrepreneur

ving to venture into Project. While expanding a current business or while venturing into new business, entrepreneurs are often faced with the dilemma of zeroing in on a suitable product/line.

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