

Republic of Egypt

an Drug Authority

inistration of Operations

actories of medical devices



جمهورية مصر العربية

هيئة الدواء المصرية

الإدارة المركزية للعمليات

مصانع المستلزمات الطبية

Certificate of Good Manufacturing Practices

This certificate conforms to the format recommended by the World Health Organization

1. **Purpose of this certificate:** To be introduced to Ministry of Health of Iraq for the purpose of Export.

2. **Certificate No:** 17-01MD/2021-01

3. **Serial No.:** 892 /2021

4. **Name and address of site:** Ameco Medical Industries Industrial zone B4-Plot 119 East 10th of Ramadan city , Egypt

5. **Manufacturer's license number:** 11/2018091900002 (License issued from Industrial Development Authority)

6. On the basis of the inspection carried out on 28/07/2021 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the products and activities listed in the Table below

Table 1:

Product	Classification	Activities
Central Venous Catheter Kit	IIb	Extrusion , Injection , Assembly , Packing & Sterilization .
Single Lumen short term Haemodialysis catheter kit	IIa	Extrusion , Injection , Assembly , Packing & Sterilization .
Dual Lumen short term Haemodialysis catheter kit	IIa	Extrusion , Injection , Assembly , Packing & Sterilization .
Dual Lumen short term Smart Haemodialysis catheter kit	IIa	Extrusion , Injection , Assembly , Packing & Sterilization .
Triple Lumen short term Haemodialysis catheter kit	IIa	Extrusion , Injection , Assembly , Packing & Sterilization .
Triple Lumen short term Smart Haemodialysis catheter kit	IIa	Extrusion , Injection , Assembly , Packing & Sterilization .
UniQath Dual Lumen short term Haemodialysis catheter kit	IIa	Extrusion , Injection , Assembly , Packing & Sterilization .
Sterile Long term Single lumen haemodialysis catheters Kits	II	Extrusion , Injection , Assembly , Packing & Sterilization .
Sterile Long term Twin lumen Haemodialysis catheters kits	III	Extrusion , Injection , Assembly , Packing & Sterilization .
Sterile long term dual lumen haemodialysis catheters Kits	III	Extrusion , Injection , Assembly , Packing & Sterilization .
Sterile Long term X split dual lumen	III	Extrusion , Injection , Assembly , Packing

Address : 51 Wezaret El Zeraa St. Al agouzah, Giza, Cairo, Egypt.

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Haemodialysis catheters kits		&Sterilization .
Sterile Long term Y split dual lumen Haemodialysis catheters kits	III	Extrusion , Injection ,Assembly , Packing &Sterilization .
Acute Peritoneal Catheter Kit	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization .
Introducer Needle	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization .
Guide Wire	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization .
Permthane Peritonal Catheter Kit	IIb	Extrusion , Injection ,Assembly , Packing &Sterilization .
Sheath Introducer	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization .
Double Loop Ureteral Stent (DLU)	IIb	Extrusion , Injection ,Assembly , Packing &Sterilization .
Ureteric Catheter Size	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization .
Nephrostomy Catheter & Kits	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization .
Supra-Pubic Cystostomy Kit	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization .
Nephro-Cutaneous Dilator Set and Sheaths	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization .
Biopsy Needles	IIa	Inspection , Packing & Sterilization
Ureteral Access Sheath	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization
Urodynamic Catheters	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization
Ureteral Balloon Dilator	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization
Two & three way Latex Silicone Coated Urethral Balloon Catheter	IIa	Inspection , Assembly , Packing & Sterilization.
Two & three way Total Silicone Urethral Balloon Catheter	IIa	Inspection , Assembly , Packing & Sterilization.
Ureteral Stone Basket	IIa	Extrusion , Injection ,Assembly , Packing &Sterilization
Ureteral Sequential Dilator Set	IIa	Extrusion , Injection ,Assembly , Packing

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		& Sterilization
Injection Needles	Ila	Extrusion, Injection ,Assembly , Packing & Sterilization
Nelaton Catheter	Ila	Inspection, Welding, Assembly, Packing & Sterilization
Guide Wires	Ila	Inspection ,Extrusion, Injection ,Assembly , Packing & Sterilization
Y-Set For Trans Urethral Resection Wash	I sterile	Inspection, Welding, Assembly, Packing & Sterilization

- The responsibility for the quality of the individual batches of the medical devices manufactured through this process lies with the manufacturer.
- This certificate remains valid until 27/07/2022. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Dr. Rabab Balnaaw
On behalf of Dr. Rabab
Medical Device Inspection Manager
23/8/2021

Dr. Amal Hegazi
Factories Inspection General Manager
23/8/2021

Authenticated
Dr. Yasin Ragaey
Head of Central Administration of Operations
23/8

Note: Not valid without stamp

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