



هيئة الدواء المصرية

جمهورية مصر العربية  
هيئة الدواء المصرية  
الإدارة المركزية للعمليات  
إدارة التفتيش على المصانع  
وإدارة التفتيش على المستلزمات الطبية والكواشف  
المعملية  
وحدة التفتيش على مصانع المستلزمات الطبية

## Certificate of Good Manufacturing Practices

This certificate is issued as per WHO TRS No 908 of 2003

- 1. Purpose of this certificate:** To be introduced to Ministry of Health of **Ecuador** for the purpose of Export.
- 2. Certificate No:** 11/2022
- 3. Name and address of site:** Ameco Medical Industries –industrial zone B4-Plot 119 East 10<sup>th</sup> of Ramadan city, Egypt
- 4. Manufacturer's license number:** 312018091900002 (License issued from Industrial Development Authority)
- 5. On the basis of the inspection 28/10/2021 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the activities listed in the Table 1 below and list of products described in products list attached to this Certificate**

Table 1:

Production line	Activities
Central venous catheter & accessories	Extrusion , Injection ,Assembly , Packing &Sterilization .
Hemo dialysis catheter & accessories	Extrusion , Injection ,Assembly , Packing &Sterilization .
Urology catheter & accessories	Extrusion , Injection ,Assembly , Packing &Sterilization .
Gastroenterology catheter and accessories	Extrusion , Injection ,Assembly , Packing &Sterilization .
PVC catheter (Nelaton)	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 27/10/2022 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. Sally Abd El Rasoul

Sally Abd El Rasoul  
Medical Devices & Invitro diagnostic inspection manager



Authenticated:  
Yasin Ragaey

Head of Central Administration of Operations

Note: Not valid without stamp

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