



For A Healthier Africa  
**AFRiSUMMIT**

2<sup>nd</sup> - 5<sup>th</sup> November 2025  
Hilton Grand Nile Hotel, Cairo - Egypt



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# **Egypt's Pivotal Role in Africa's Transformation from Importer to Medical Device Powerhouse**

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# Agenda

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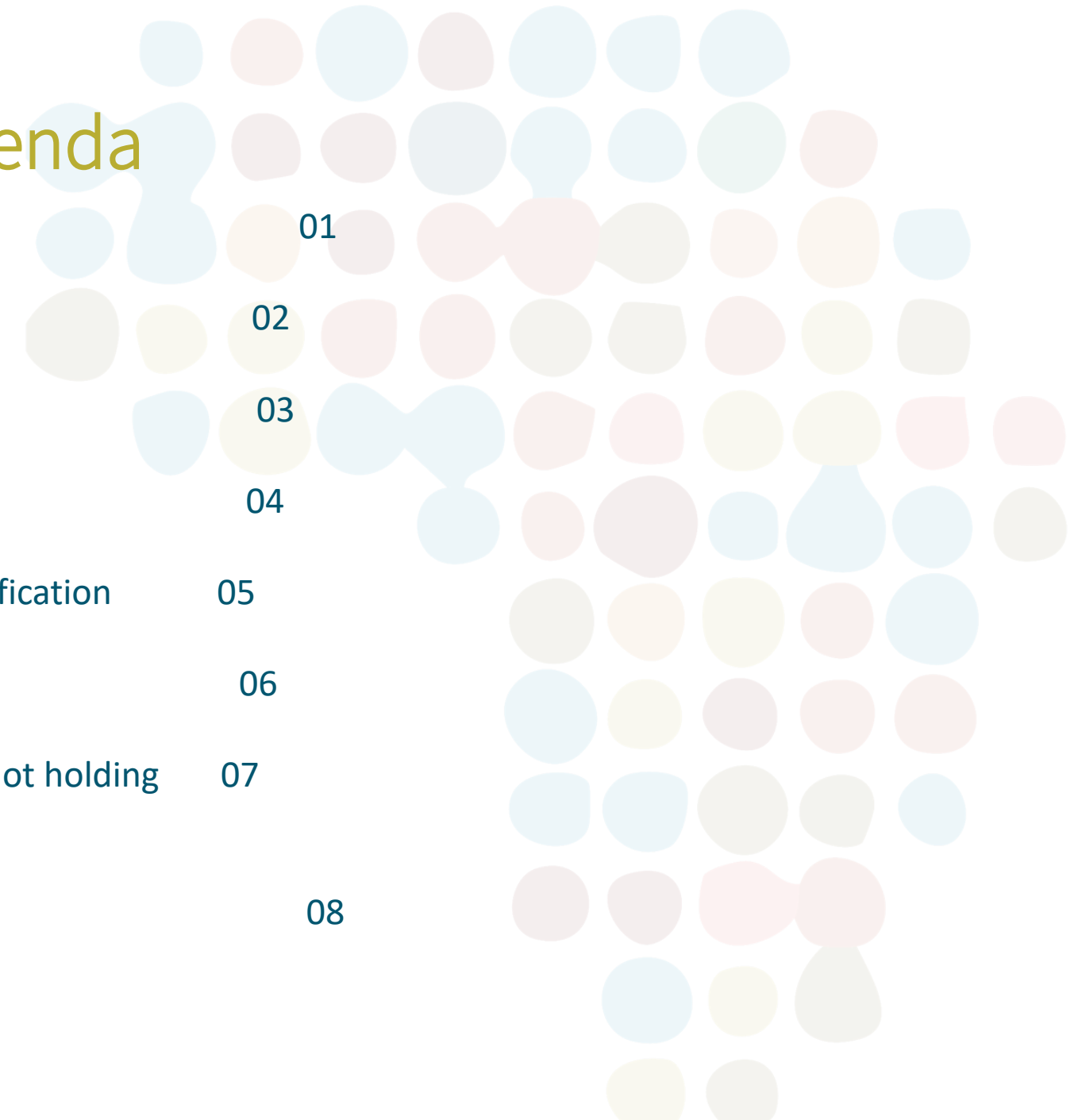
06

Registration of Locally Manufactured Medical Devices not holding  
International Quality Certificates

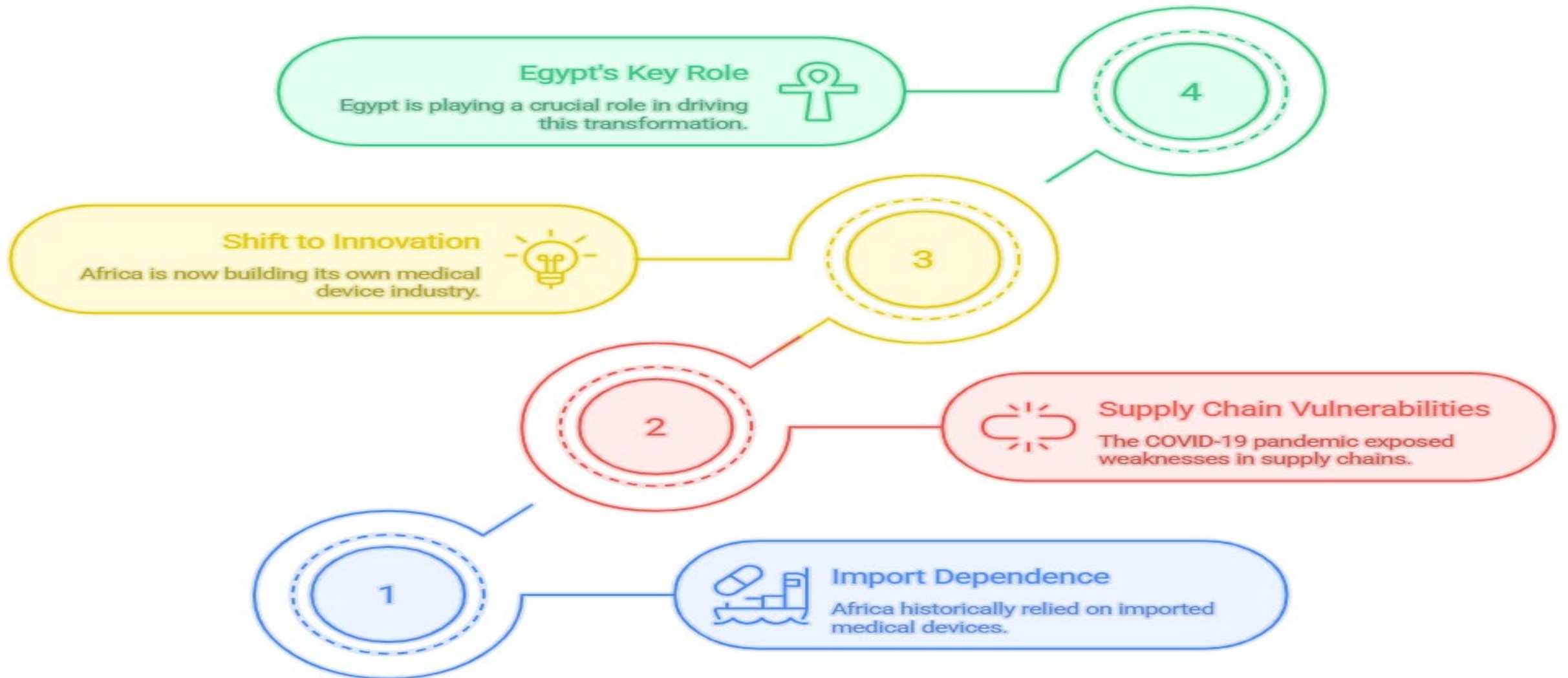
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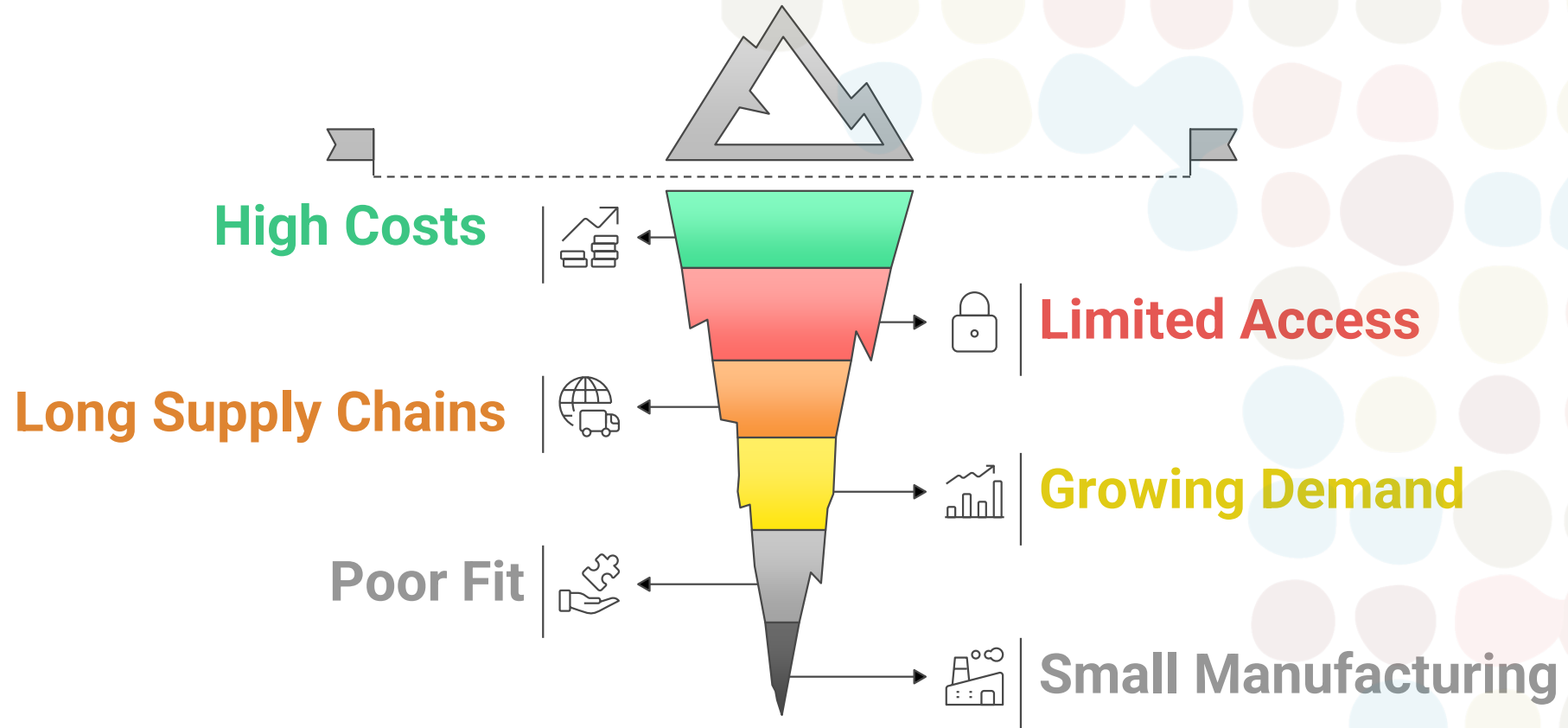


# Introduction



# Medical Device Challenges in Africa

Most Medical Devices are imported



# Local Manufacturing of Medical Products in Africa

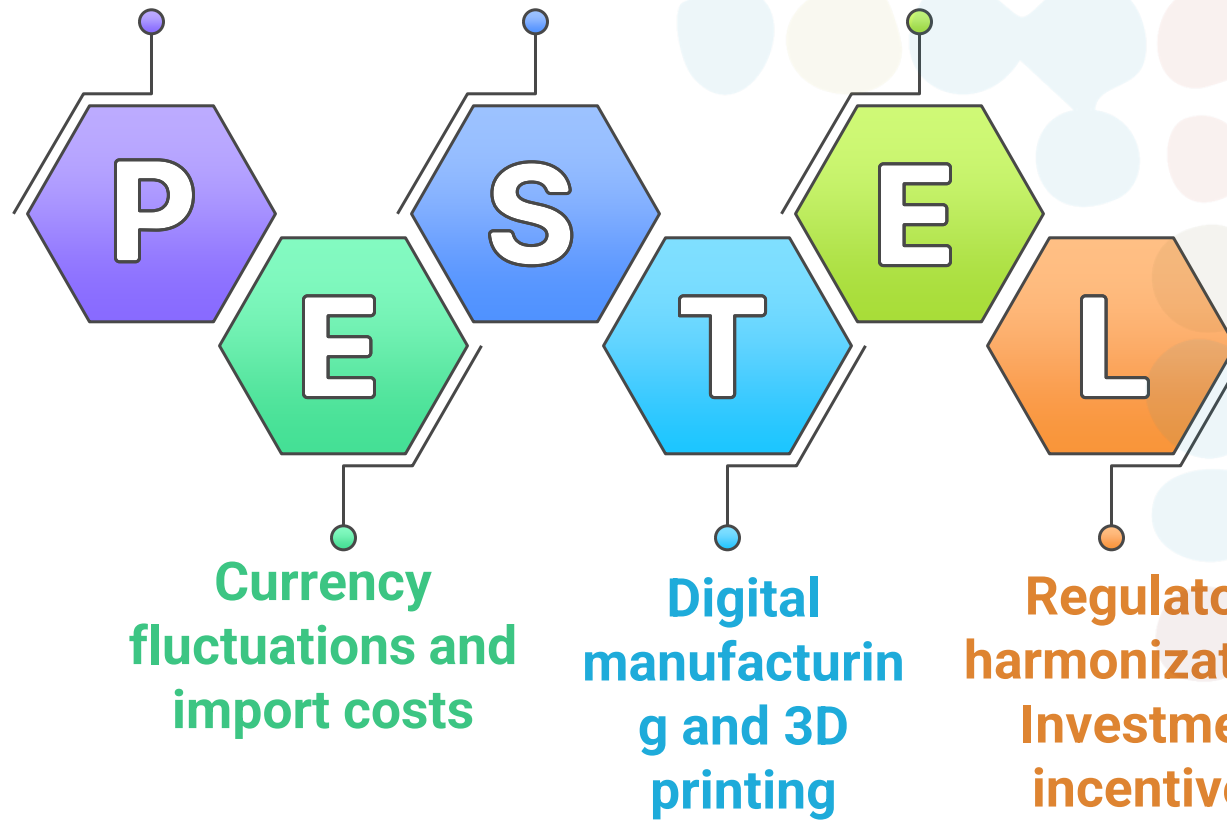


# Driving forces toward Manufacturing Shift

local manufacturing policies & AFCFTA.

Population growth and urbanization

Resource availability



# Egypt's Role: From Regional Hub to Powerhouse



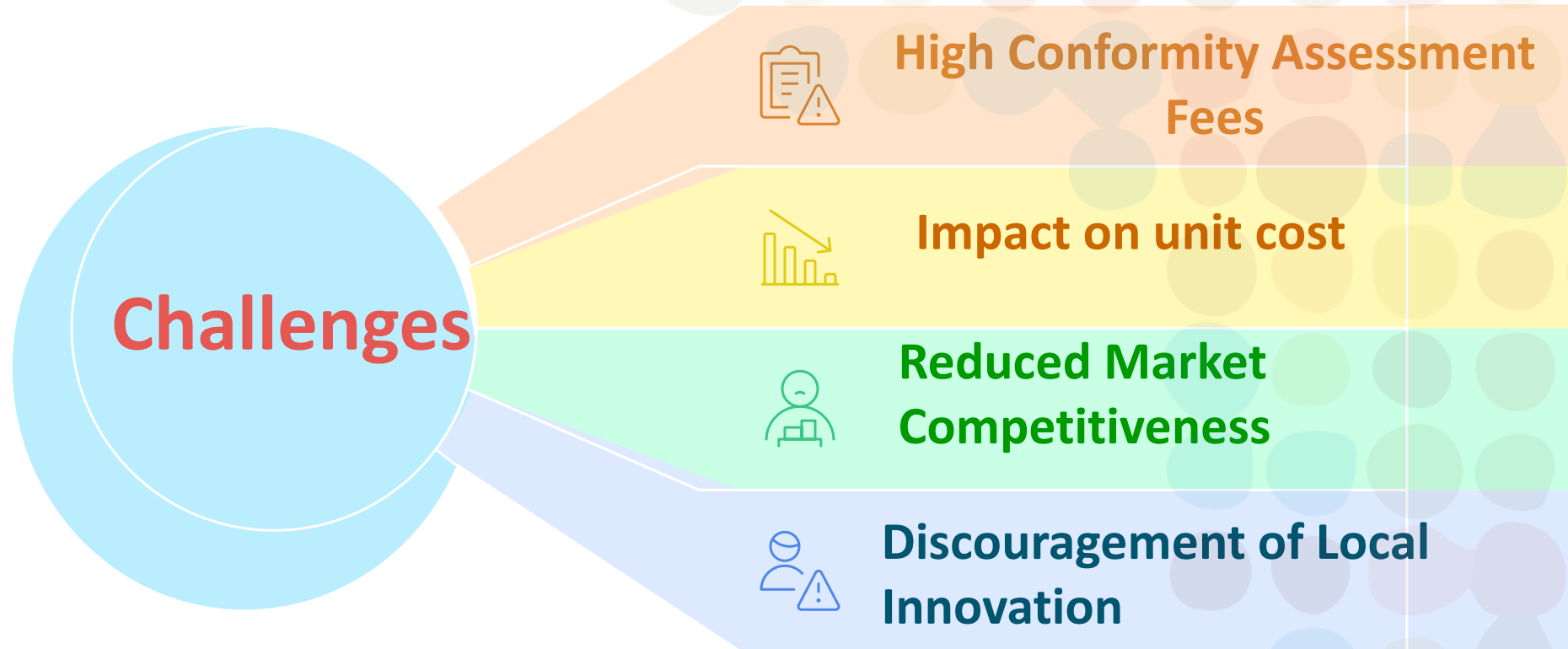
## \* African Health Leadership

- Supports African regulatory harmonization
- Exports devices and expertise to African nations

## \* Government Support

- Vision 2030 industrial growth strategy
- The Egyptian Drug Authority (EDA) support
- Boosting Medical local manufacturing

# Challenges Faced by Medical Devices in Obtaining Certification



# Registration of Locally Manufactured Medical Devices not holding International Quality Certificates

## ISO 13485 Compliance

Meets advanced local standards for quality management systems.

## CE-Marked Equivalence

Ensures global market access through harmonized regulatory standards.

## GMP Enforcement

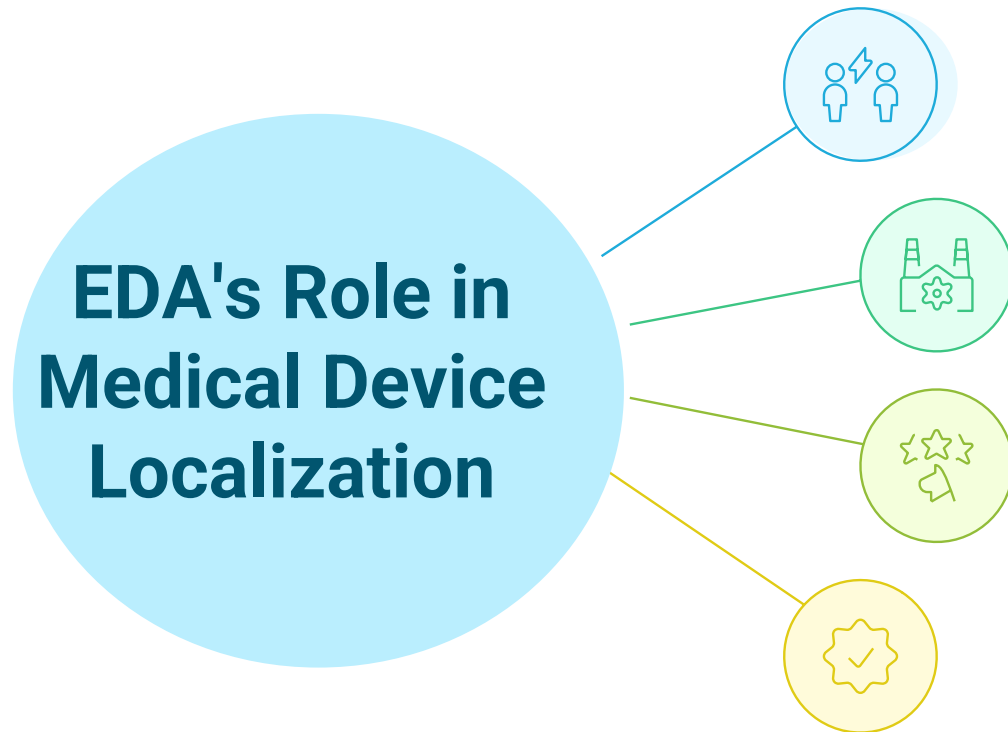
Enforces basic local manufacturing standards for product safety.

## IMDRF Harmonization

Aligns with international frameworks for basic Regulatory alignment.



# EDA's Strategies for Medical Device Localization



**Periodic Meetings**

**Industrial Localization Committee**

**Adoption Local Evaluation Mechanisms**

**Updating Registration Regulations**

# Conclusion & Call to Action

## Africa's Medical Device Revolution *is underway*

### Egypt: Leader & Enabler

- Emerging as a leader
- An enabler of this transformation



The Journey



**From Importer  
to Innovator**

Will Define Africa's Healthcare Future



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**TOGETHER →  
MADE IN  
AFRICA  
FOR AFRICA.  
FOR THE WORLD.**

**THANK YOU**