Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

1927-2017 FICCI @90

Unifying Efforts against Counterfeiting Medical Devices

22nd Asian Harmonization Working Party Annual Meeting

4-8 December, 2017 I New Delhi

Nazeeh Alothmany, PhD

Vice Executive President for Medical Devices and Equipment

Saudi Food and Drugs Authority

MEDICAL DEVICES Definition

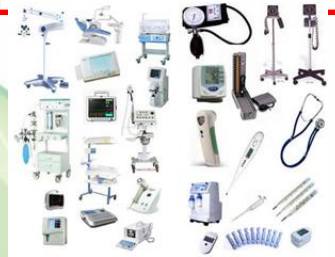
- Instrument
- Apparatus
- Implant
- Machine
- Appliance
- Software
- Material
- Other similar or related article

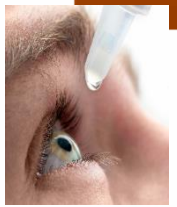
which doesn't achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

- Diagnosis
- Prevention
- Monitoring
- Treatment
- Alleviation
- Compensation

} disease / injury

- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices





A variety of medical devices

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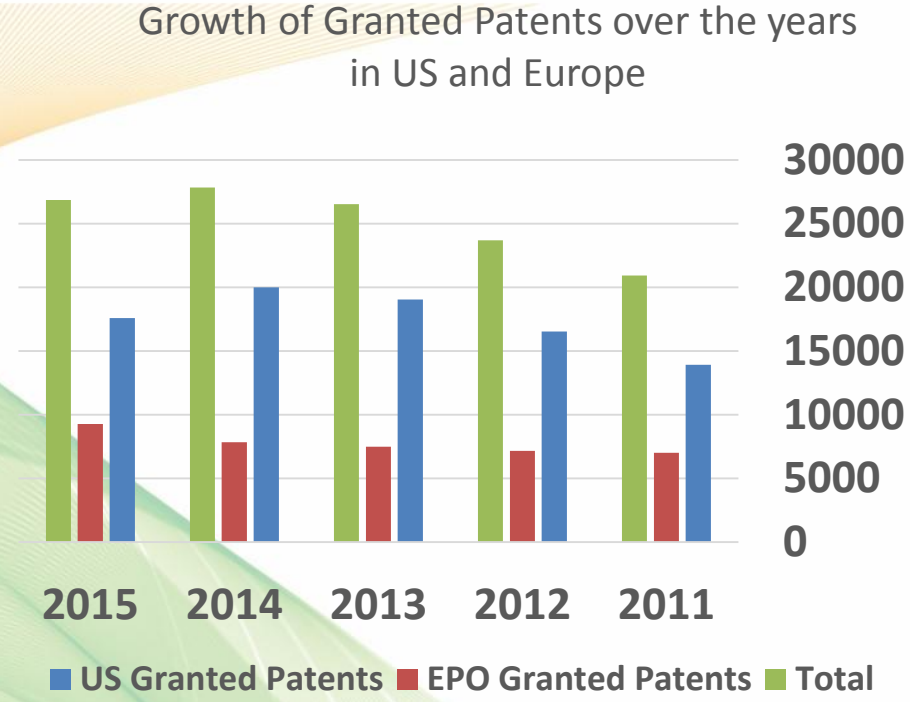
Growth in Medical Devices Industry



- Data Source (USPTO, EPO) websites
- This is only in US and Europe
- Number of Applications is higher
- Not all inventors apply for patents

challenge

WHO Definitions for Counterfeit

- There is currently no universally agreed definition amongst Member States of what used to be widely known as ‘Counterfeit medicine’.
- WHO uses the term Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical product until a new definition is agreed.
- The term ‘counterfeit’ is widely used to include falsified, unlicensed, falsely packaged, stolen and substandard medical products.
- WHO defines Counterfeit as:
  - A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of ingredient(s) or with fake packaging.

1. “Definitions of SSFFC Medical Products”, WHO - Essential Medicines and Health Products Regulations, URL: http://www.who.int/medicines/regulation/ssffc/definitions/en/ Last Seen: May 2nd 2017

Italian Agency Pharma- Impact

- WHO created the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to raise awareness, mobilize nations, and draft international legislation.
- The task force published handbook at the end of 2010 demanding collaboration between nations to put legislations and regulations on manufacturers, importers, distributors, sale points and health facilities dealing with medical devices to combat counterfeit products.
- According to the World Health Organization (WHO), more than 8% of the medical devices in circulation are counterfeit.

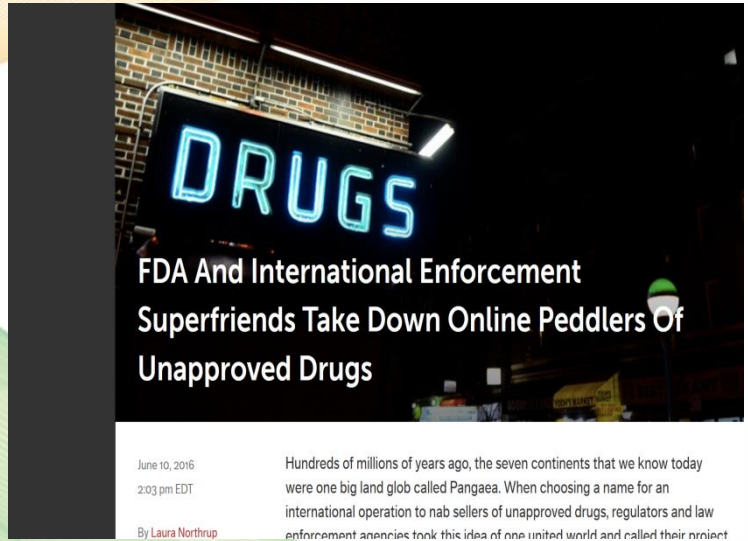
"Impact- International Medical Products Anti-Counterfeiting Taskforce. Facts, activities & Documents developed by the working group 2006-2010. Agenzia Italiana del Farmaco. Vr. URL: http://apps.who.int/medicinedocs/documents/s20967en/s20967en.pdf. Last visited May 2nd 2018.

Asia Pacific Economic Forum, Life sciences Innovation forum (APEC LSIF) Anti-counterfeit Action Plan

- APEC economies should work together to collect data on counterfeit medical products
- APEC economies should establish harmonized legislation and penalties for prosecuting medical product counterfeiters
- Many counterfeit elements enter into APEC economies through internet sales. Better internet prevention strategies and awareness is needed
- Track and trace technologies are important, but may are not the sole solution
- APEC cooperation on counterfeit medical product public awareness is also needed

"APEC LSIF INITATIVES – Meedical Device Global Harmonizatation and Anti Counterfeit Medical Product Global cooperation", by Jeffery Gren, APEC LSIF Regulatory Harmonization Steering Committee, Hiroshima Japan 2010, URL: http://www.trade.gov/td/health/apec_LSIF_gren2010.pdf, last accessed May 3rd 2017

FDA Project Pangea – Internet Sale



- Operation Pangea VIII was a project of massive scope, a lightning move by 115 countries that resulted in more than 2,400 websites being taken offline and the seizure of $81 million worth of potential dangerous illegal medicines and medical devices worldwide.
- Global Strategic Framework for counterfeit and substandard medical products (sometimes known by the acronym SSFFC, for Substandard, Spurious, Falsely-Labeled, Falsified, Counterfeit) to help protect consumers by reducing their exposure to counterfeit and substandard medical products. The framework is focused on three pillars: Prevention, Detection, and Response.
- Counterfeit Medical devices detected in the supply chain in variety of products ranging from bandages, contact lenses, spinal implants and aortic pumps.

"A Global Fight Against Dangerous Counterfeit and Unapproved Medical Products: From Operation Pangea to a U.N. Global Strategic Framework" Posted on June 30, 2015 by FDA Voice, URL https://blogs.fda.gov/fdavoice/index.php/2015/06/a-global-fight-against-dangerous-counterfeit-and-unapproved-products-from-operation-pangea-to-a-u-n-global-strategic-framework/, last visited May 2nd 2017

European Union Impact Assessment on Counterfeiting devices

- Proposed Policy Action to tackle counterfeiting devices:
  1. Develop best practice guide to deal with counterfeiting
  2. Write a code of conduct for any company to report counterfeiting
  3. Enhance information collection and share databases with member states
  4. Increase Traceability and use UDI to track devices
  5. Take actions against sales on the internet
  6. Establish a code of conduct for procurement (private and public) to secure purchasing channels

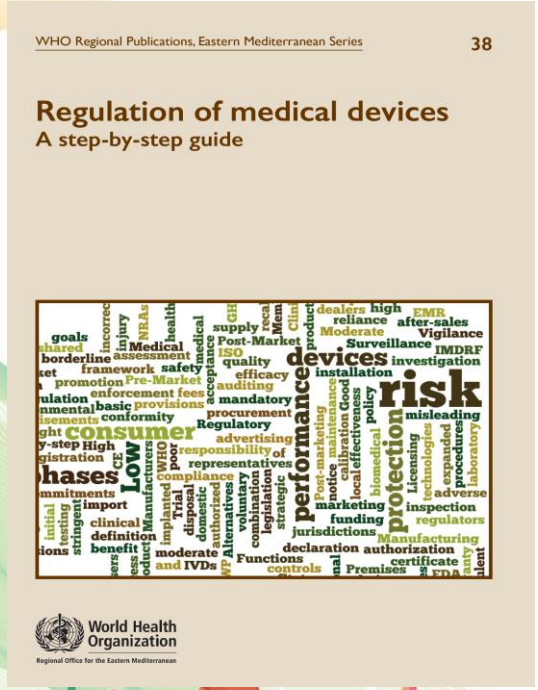
"Impact Assessment of Policy Options for Combating Counterfeiting of Medical Devices and for Developing Safer Distribution Channels for Parallel Trade in Medical Devices", Europe Economics, URL http://europe-economics.com/, last visited May 2nd 2017

Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products

- SSFFC medical products from all main therapeutic categories have been reported to WHO including medicines, vaccines and in vitro diagnostics.
- In 2013 WHO launched a global surveillance and monitoring system to encourage Member States to report SSFFC incidents in a structured and systematic format
- Over 920 medical products have so far been reported representing all main therapeutic categories and representing both innovator and generic medicines.
- Unregulated websites supplying medicines, particularly those concealing their physical address or landline telephone number are frequently the source

"Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products". WHO fact sheet. Prepared on January 2016. URL: http://www.who.int/mediacentre/factsheets/fs275/en/. Last visited May 2nd, 2017.

WHO Recommendations



- The opportunity of establishing one or more central databases within a region should be explored and implemented where appropriate.
- The feasibility of developing a database for notification and surveillance of counterfeit medical products should also be explored.

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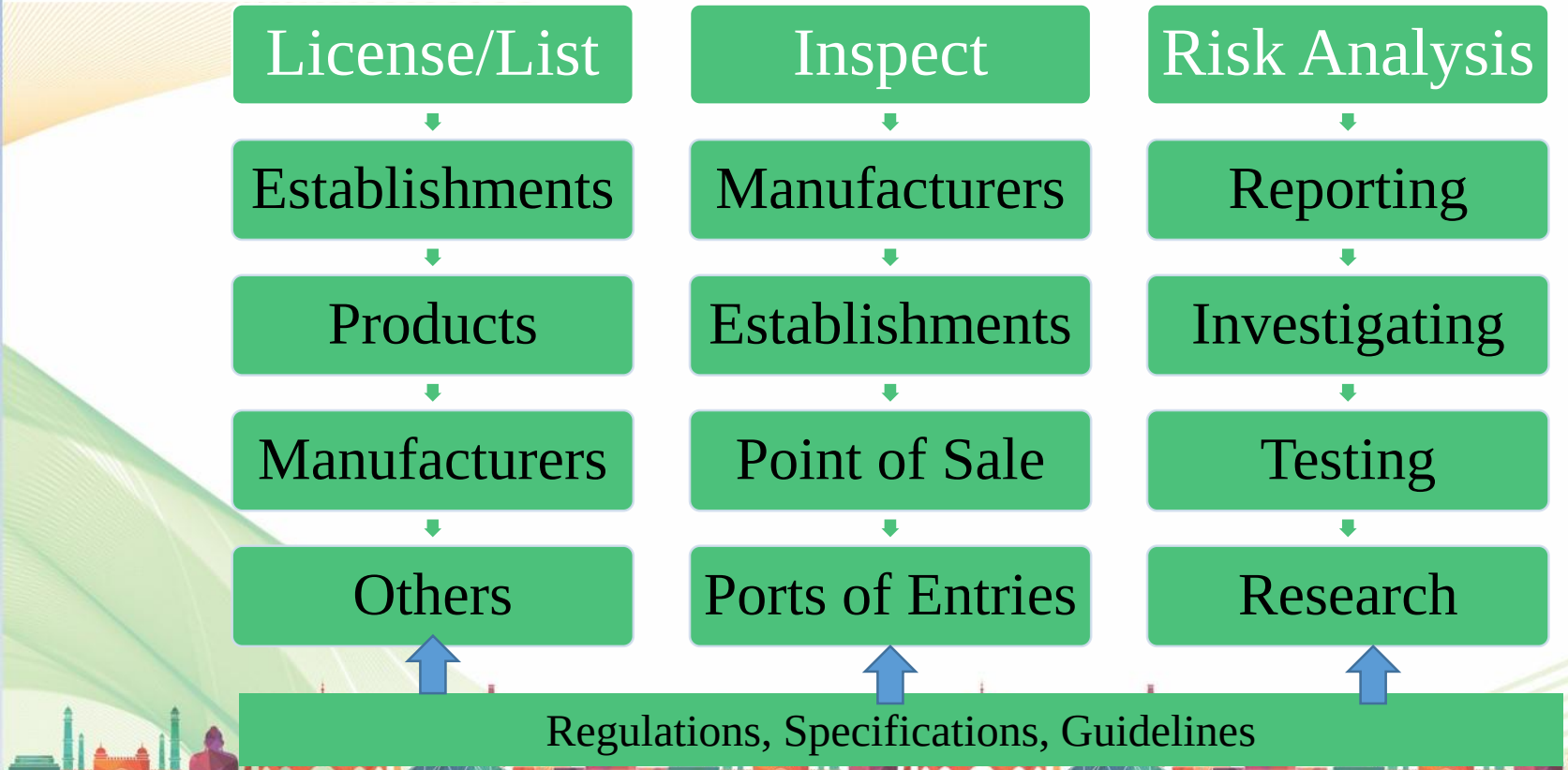
SFDA Experience

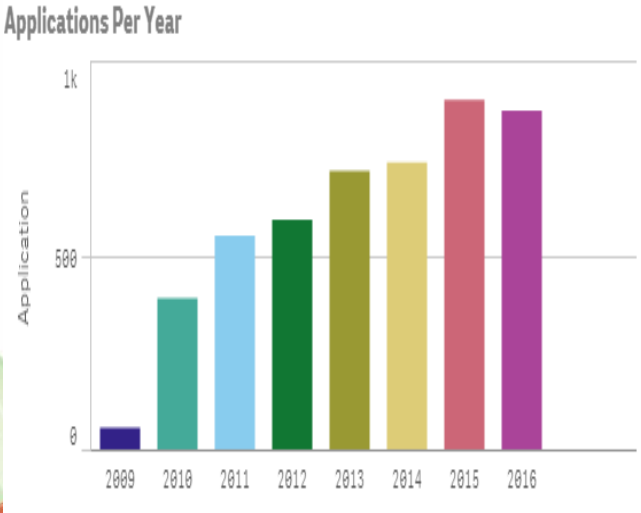
Inspection, Surveillance teams

SFDA Activities

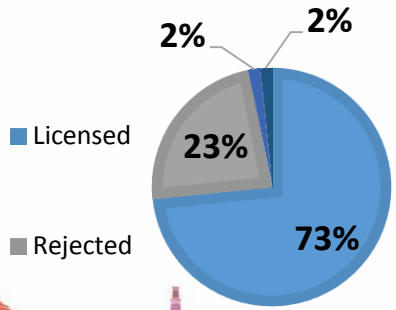


Medical Device Establishment License (MDEL)

All establishments (supplier, distributor, manufacturer) are not entitled of handling any medical devices in the Saudi market only when obtaining a license for their establishment (MDEL).



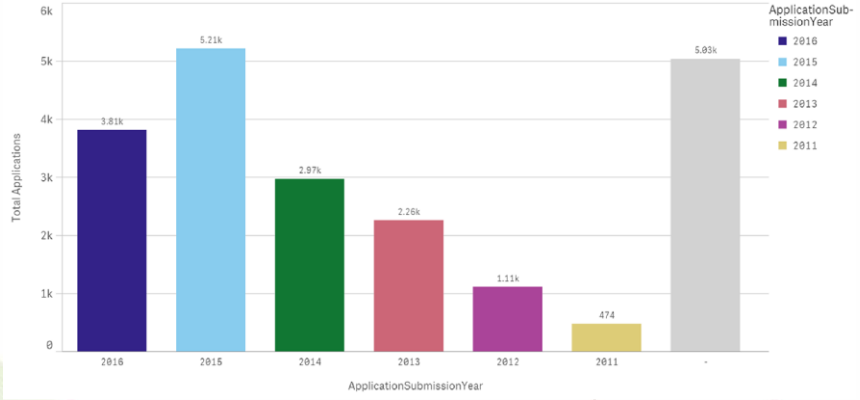
IMPORTER AND DISTRIBUTERS



Medical Device Market Authorization (MDMA)

Handling of medical devices in the Saudi market is not eligible, only when obtaining a permission to market the (MDMA)

سنة تقديم الطلب	2011	2012	2013	2014	2015	2016	مسودات لم نقدم	المجموع
	474	1110	2258	2969	5212	3812	5033	20868



MDMA Statistics

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If the device is not pre-authorized in Saudi, SFDA will block it at the ports of entry

Ports of Entry Statistics

(2009- Quarter3 2016)

Cleared shipments

(2009- Quarter3 2016)

	MD	IVD	Non-Medical IVD	Total
Number of cleared Shipments	61,702	32,877	427	95,106
Number of cleared Items	138,660	46,302	620	185,580
Quantity of cleared items	7,697,067,476	715,754,876.80	534,272	8,711,997,486
Value of cleared items	25,504,242,260	11,201,656,874	65,734,676	36,771,633,809

Rejected shipments

(2009- Quarter3 2016)

	MD	IVD	Non-Medical IVD	Total
Number of rejected Shipments	2,456	1,951	40	4,447
Number of rejected Items	16,207	15,632	199	30,914
Quantity of rejected items	64,129,677	8,227,712	281,070	72,663,461
Value of rejected items	366,702,654.40	103,736,580	1,653,150	**472,092,386.40**

Forged Documents Detected by SFDA

- Trends in Forging Documents:
  - MHRA Free sale certificates (multiple cases)
  - Label Related:
    - Editing/Change Manufacturer name
  - Certificate Related
    - Adding additional products into certificates (ISO 13485, Free sale, CE certificates)
    - Editing SFDA Market authorization
  - Instruction for Use (IFU)
    - Removing/adding comments
  - Attestations:
    - Authorized Representative forging attestations on behalf of manufactures
- SFDA Champions: Omar Aljarallah, Abdulaziz Alkhalifa, Mohammed Muhanna, Abdullah Alsobai, Marwan Alduhami, Tuki Alturki, Mohammed Zakour, Abdullah Aljaser, Abdullah Alshammari, Ahmed Aljaser, UL, TUV, BSI

Sell an Authorized, deliver an Un-Authorized

- Distributors obtain market authorization for products using proper documentation and claim to have FDA approval with health facility.
- Products shipped to facility come from another factory (i.e. not FDA approved, submitted documents don’t apply to that factory)
- Products picked at ports of entry after inspection and shipment was rejected
- Hospital escalated the issue against SFDA
- Once situation explained to hospital, the distributor was black listed with the hospital
- Now Hospital refuses to purchase equipment not authorized by SFDA.

CE Certificate valid, ISO13485 and audit report expired

- These two certificates are valid.

The audit report provided was more than 1 year old (02-Oct-2015) and therefore not acceptable.

EC Design Examination Certificate
Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

[redacted]

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 281863 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: TD15-002 Arc-Arc Mini Design Dossier dated 06-06-2015

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 1540_11e_Report_TFR_ARC_V1 dated 2015-06-14

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	281863 MRA
Certificate unique ID	170624174
Effective date	2015-06-14
Expiry date	2020-06-13
Frankfurt am Main	2015-06-14

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

EC-CERTIFICATE
(Full quality assurance system)

This is to certify that the company

[redacted]

rance system which applies to the products

ed by DQS Medizinprodukte GmbH,
it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Implants and Instruments for Interventional Minimal Invasive Therapy according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

[redacted]

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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Trademark Counterfeiting

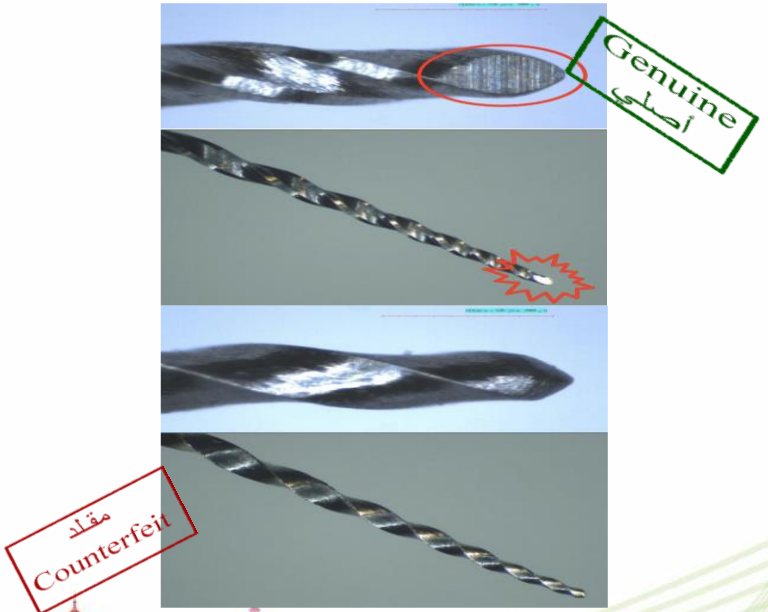
Aerochamber counterfeit product. Reported by authorized representative, detected by Saud Aldossary from SDFA.

Contact lenses reported by manufacturer, Saud Aldossary tracked the product, compared bills and concluded that it is counterfiert.

Trademark Counterfeiting

Dental file marketed in KSA at Newmat French company, reported by a patient because it broke. Investigation lead to discovering that it is a counterfeit product.

Dents Ply reported by authorized representative, investigation resulted in identifying as counterfeit.



Trademark Counterfeiting

- Counterfeit Contact lenses ; odel: FASHION LOOK.
- Discovery Method:
  - Adverse event reported by an end user claiming that he could not remove the lense from his eyes. SFDA inspected and tested the products and discovered that the product has a fake CE mark and conformity body number

Fake
Conformity
Body number

Trademark Counterfeiting

“Sugar style” sugar stripes, suppose to be distributed free by Ministry of health, box is changed and sold separately

Authorized representative reported counterfeit product in the market, inspection team investigated, requested receipts, samples from original and counterfeit, manufacturer was contacted and product was proved to be counterfeit

Waleed Alsubaihi

Trademark Counterfeiting

Pregnancy tests by HCG counterfeited

Inspection visits lead to suspecting the products. Receipts were compares, samples were tested and identified as counterfeit

Trademark Counterfeiting

Litman Stethoscope Counterfeited

Reported by the authorized representative , inspected and after communicating with the manufacturer we determined that it is a counterfeited product

Walled Alsubahi

Trademark Counterfeiting

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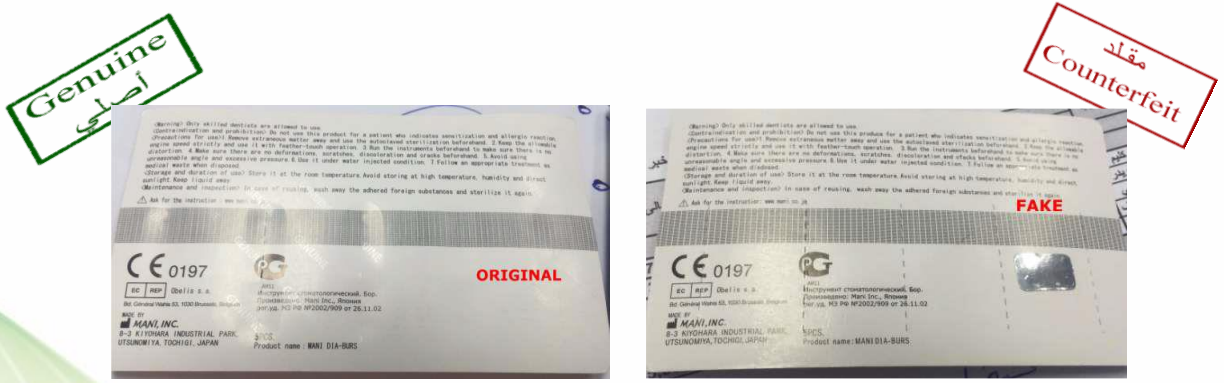
Mani Root canal files Counterfeited

Reported by the authorized representative , inspected and after communicating with the manufacturer we determined that it is a counterfeited product

Abdulrahman Alkhulaifi



Trademark Counterfeiting

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Counterfeited natura silner Medical socks

Reported by the authorized representative , inspected and after communicating with the manufacturer we determined that it is a counterfeited product by Ahmad Alamoud

مقلد
Counterfeit

Genuine
أصلي

Trademark Counterfeiting

Dental Glue by PRIME & BOND NT

An Alert was sent by the manufacturer to warn against counterfeited product being marketed globally

Saud Aldossary

Trademark Counterfeiting

Lenses cleaner "Refreshing" tampering label to change expiration date

Consumer Protection requested product verification, after inspection, SFDA discovered that the label was edited to change the expiration date

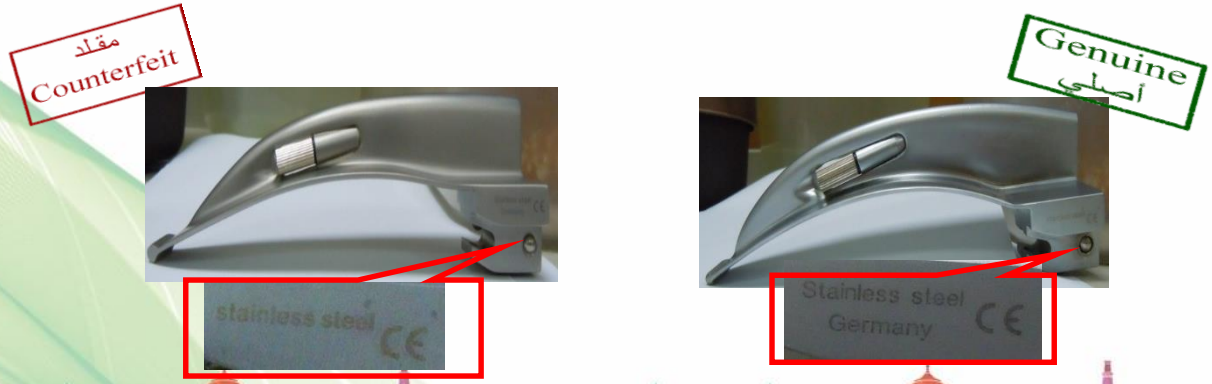
Waleed Alsubahi

Trademark Counterfeiting

Counterfeit laryngoscope sold as a genuine “Riester”.

Captured by port inspectors, when compared with original product, they discovered that it is a counterfeit product

Inspector: Waleed Alsubahi



Trademark Counterfeiting

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Another counterfeited product sold as genuine "**Riester"**

Captured by port inspectors, when compared with original product, they discovered that it is a counterfeit product

Inspector: Waleed Alsubahi

Trademark Counterfeiting

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Counterfeited Needles for glucose meter sold as genuine “Accu-Chek”

Field inspection team suspected the product and when verified it, it turned out to be counterfeit

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SFDA Initiative

United Against Counterfeit Devices and Equipment

Action is needed !

- We have a commitment of ensuring safety and efficacy of devices to protect patients around the globe
- Multiple authorities around the globe are noticing the problem
- Current efforts are mostly focusing on drugs
- Medical device community needs to step forward
  - Form a taskforce of MEDICAL DEVICES Experts to tackle this problem
- SFDA re-state the request to WHO to form a workgroup dedicated for Medical devices

Data Sharing Platform for Regulators

- SFDA launched an online portal for regulators to upload information on counterfeited products detected in their area
- www.sfda.gov.sa/
- We urge you to visit the website, submit a request to join the initiative and we will contact you to with instructions to proceed.

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We care about what matters !

Thank you !