

Anticounterfeiting technologies for medical device packaging



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Abbreviations

Abbreviation	Definition
WHO	World Health Organization
FDA	Food and Drug Administration
ISO	International Organization for Standardization
RFID	Radio Frequency Identification
IR	Infrared
UV	Ultraviolet
PE	Polyethylene
PP	Polypropylene
PET	Polyethylene Terephthalate
QR	Quick Response
DNA	Deoxyribonucleic Acid
HIV	Human Immunodeficiency Virus

Introduction

We live in an era of sophisticated medical facilities, where devices range from basic tools such as the simplest injecting needle to complex robotic surgical systems. Each plays a crucial role in the healthcare industry, however, their effectiveness depends on the coordinated efforts of various sectors to ensure their proper function. One such domain is medical device packaging, which not only enables the use of the device but also plays a vital role in saving lives.

The medical device industry comprises companies that develop or manufacture a medical device and/or provide services for the same. As per the report by Research and Market, the global medical device market will reach \$745.0 billion by 2030, growing by 5.0% annually through 2030.

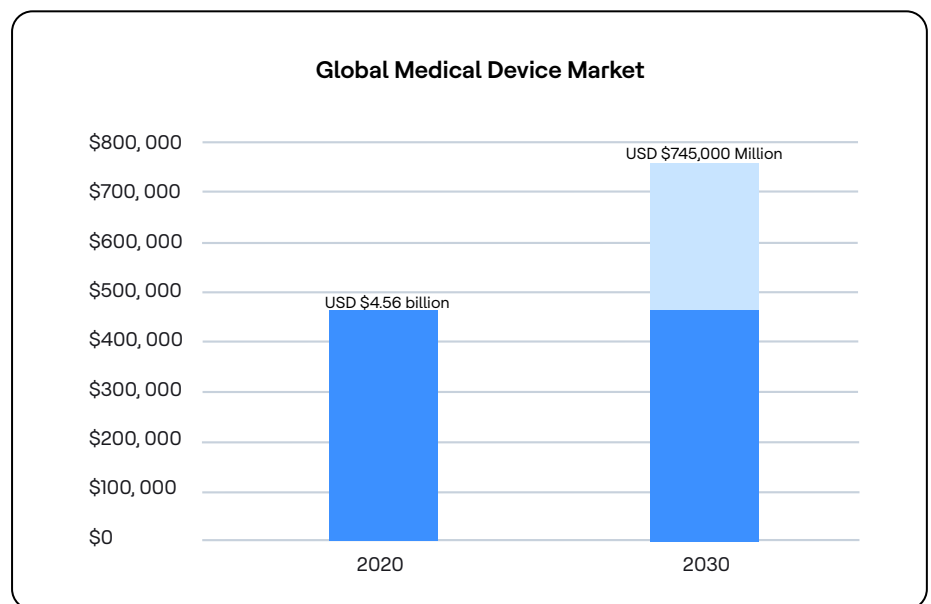


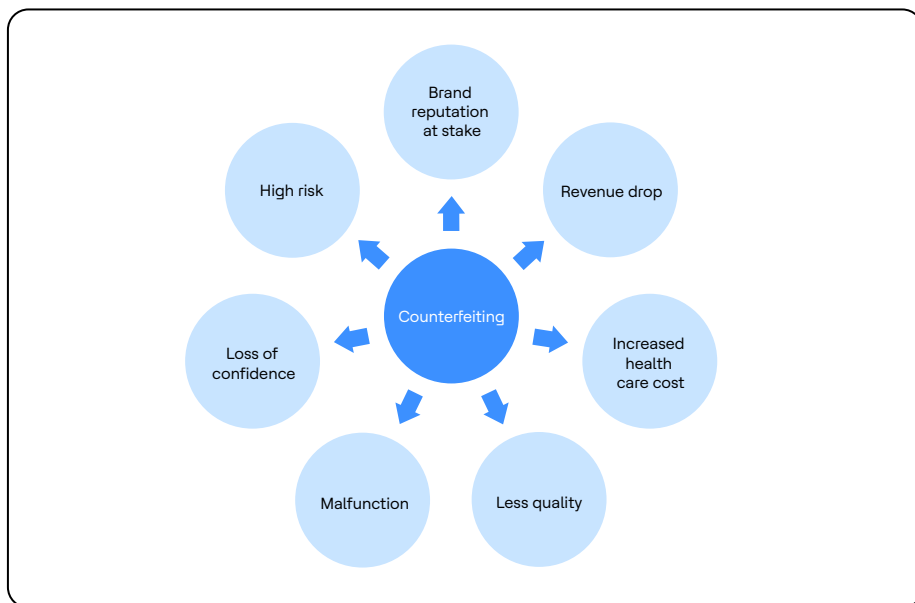
Figure 1 Global medical device market trend (As per the Research and Market report, April 2021)

Despite the futuristic nature of medical devices and their associated systems, misconduct still occurs in the form of counterfeiting. Counterfeiting involves intentionally modifying the identity of an original product and selling a duplicate version in its place. This not only jeopardizes the reputation of brands but also poses a significant threat to the end user.

Abstract

Counterfeiting has always been an issue in every sector where both the brand and the consumer are at risk. Counterfeit products are substandard in terms of safety, quality and efficacy. This whitepaper aims to shed light on the various anti-counterfeiting techniques used during packaging to address this challenge in the medical device industry.

Moreover, counterfeiting within the medical device industry can have serious consequences that may begin with small allergic reactions before advancing to bigger risks that ultimately put a patient's life at risk.



Terms and definitions

Medical device – According to the World Health Organization (WHO), “A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article intended by the manufacturer to be used alone or in combination for a medical purpose.”

Counterfeiting – The term “counterfeiting” refers to the idea of “falsifying” or “duplicating” an original product or its contents that is intended to replace the actual one.

Counterfeit device – As per the FDA, “The term ‘counterfeit device’ means a device which, or the container, packaging, or labelling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.”

Anticounterfeiting – Anticounterfeiting refers to the measures or practices followed by individuals or organizations to combat counterfeit products and secure their own products, making it extremely difficult for falsification to succeed. These measures provide a comprehensive authentication throughout the product lifecycle ensuring protection against counterfeiting at any stage.

Overt - These visible security features can be inspected through physical manipulation. They are detectable either by the naked eye or via touch, allowing easy verification.

Tamper evidence - This feature leaves visible marks or evidence when unauthorized interference or alterations occur. This creates an irreversible, visible change on the packaging, indicating that the product has been compromised.

Covert simple - Hidden security features that are not visible to the naked eye. They require additional physical tools or specific light source for authentication.

Covert sophisticated - These features are more advanced and can only be detected in laboratory environments with specialized equipment. Access to the details of these features is limited to a select group of authorized individuals.

Forensic - A subset of covert technologies, forensic features use scientific methodology for authentication. These high-technology solutions require laboratory testing or field test kits to provide verified proof of authentication.

Counterfeiting in the medical device industry

Advancements in science and technology have led to increasingly complex medical devices. However, the prevalence of counterfeiting medical devices has also risen significantly.

The World Health Organization (WHO) estimates that up to 1% of medicines available in the developed world are likely to be fraudulent. This figure rises to 10% in various developing countries and in parts of Asia, Africa and Latin America, fraudulent pharmaceuticals could account for as much as 30% of the market.

According to the WHO, an estimated one out of ten medical products in low- and middle-income countries is either substandard or duplicated.

The below graph demonstrates the percentage by which each industry is affected by counterfeit goods, with the medical device industry being impacted by 5%. Even though the percentage is lower than that of other industries, the consequences of counterfeiting in the medical industry are particularly intense.

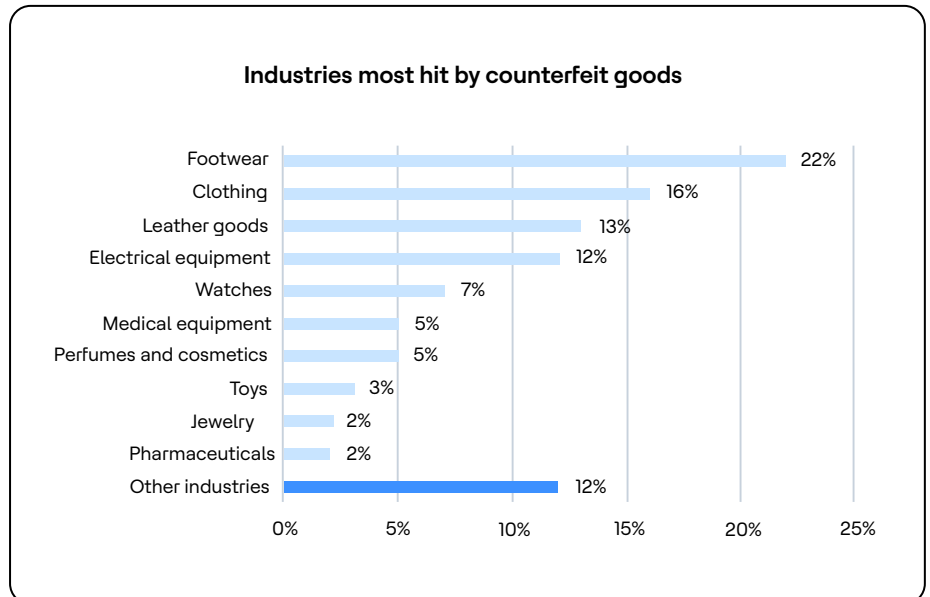


Figure 2 Industries affected by counterfeiting in percentage. (Source: OECD 2019 Study)

Below are several examples from the last 15 years of medical device counterfeiting around the world.

2020 – Coronavirus and counterfeit medical products

- Operation Pangea XIII was coordinated by INTERPOL and involved 90 countries worldwide. The agency stated that the outbreak of COVID-19 worldwide “has offered an opportunity for fast cash, as criminals take advantage of the high market demand for personal protection and hygiene products.”
- In this operation, approximately 4.4 million units of illicit pharmaceutical products were seized by INTERPOL authorities. In addition, more than 37,000 unapproved and counterfeit medical devices were seized, with the vast majority of these being surgical masks and self-testing kits (HIV and glucose).

2019 – Falsified rabies vaccines



VERORAB, powder and solvent for suspension for injection		
Product Name	VERORAB, RABIES VACCINE FOR HUMAN USE, PREPARED ON CELL CULTURES (INACTIVATED)	
Stated Manufacturer	SANOFI PASTEUR	
Presentation	Secondary Packaging (Pack/Carton)	Primary Packaging (Powder in Vial and Solvent in Prefilled Syringe)
Batch Number	NIE35	Unknown at this stage
Expiry Date	04-2019	Unknown at this stage
Date of Manufacture	23 MAY 16	Unknown at this stage
Available photographs		

Figure 3 Image by the WHO - Verorab vaccine

- Falsified Verorab® vaccines were found in the Philippines and have been reported to the WHO. Verorab is utilized to prevent rabies in people of all age groups. This vaccine can be used before or after the exposure. Sanofi Pasteur is the genuine manufacturer and owner of this vaccine, which has been used to prevent rabies since 1985. In December 2018, a public health warning was issued by the Philippines Food and Drug Administration (FDA) concerning falsified Verorab® vaccines circulating in the country. Two versions of the falsified vaccines have been identified so far (see the table above).

2012 – Contaminated epidural steroid injection

- The Center for Disease Control and Prevention identified 693 illnesses and 45 deaths in 19 states of England due to meningitis, which is a fungal infection caused by a contaminated epidural steroid injection from the New England Compounding Pharmacy Center in Framingham, Massachusetts.

2009 – NovoFine Insulin pen needles

- NovoFine Insulin pen needles were counterfeited and the counterfeit products were reported in the UK and the Netherlands. The counterfeited needles can cause infection and other adverse reactions. [[ARCHIVED CONTENT] MDA/2009/021 - Insulin pen needles: Labeled as Novo Nordisk Ltd Novofine® Needles 31G (nationalarchives.gov.uk)]

The above-mentioned are a few cases where medical devices were duplicated, largely affecting end users. As a reaction to all this, medical device companies are also constantly looking to improve their medical devices in terms of security to prevent any form of counterfeiting. The endless need for security brings in the concept of anticounterfeiting.

Anticounterfeiting

Anticounterfeiting techniques are crucial in safeguarding organizations whose products are at risk of duplication. By making packaging more convoluted and costly, brands can significantly increase counterfeiters' difficulty and expense. In the forthcoming paragraphs, a detailed explanation of anticounterfeiting will be provided, along with the types of anticounterfeiting and various technologies that brands can adopt to protect their products.

Anticounterfeiting technologies are classified into four levels ranging from simple to complex. They are:

- Overt
- Covert simple
- Covert sophisticated
- Forensic

The classification is illustrated in the below diagram.

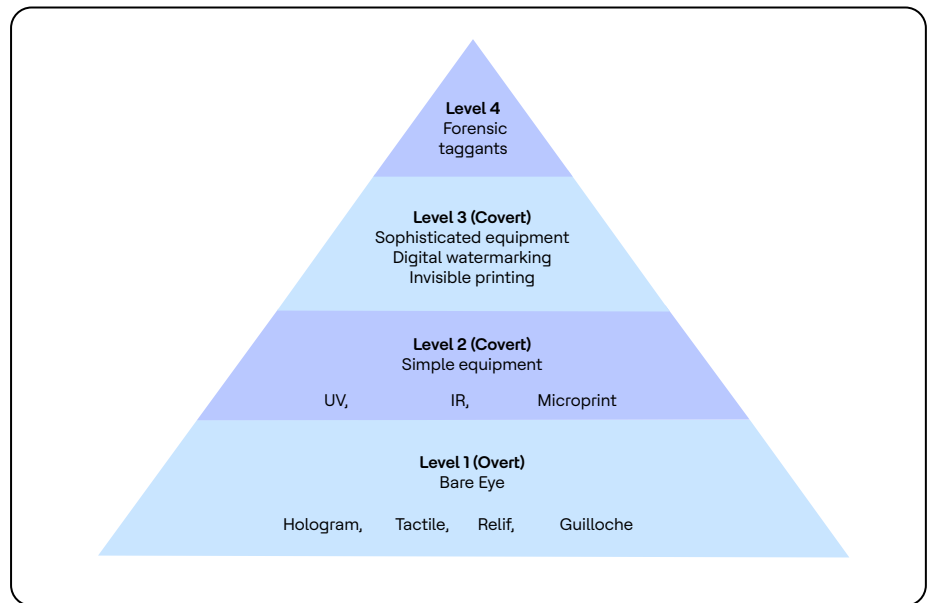


Figure 4 Anti-counterfeiting levels (www.nanomatrixsecure.com)

Overt

Despite being easily identifiable, these security features are difficult to copy when combined with multiple security elements. Successful overt measures add significant costs to the brand owner and require the end user to be educated.

The types of overt anticounterfeiting features include:

Tamper-evidence

This feature can mainly be incorporated into labels. The various types include tamper-proof labels, void labels and multi-destructible labels.

Void labels - This is a type of security label made up of bilayer material, with the base being polyester face stock that is adhesive-laminated with a metallic polyester layer. When detached, it reveals the word 'VOID' appearing several times or any other text tailored to the requirements, .



Figure 5 Void Label (Source: 3M™ Tamper Evident Label)

The tamper-evident features for medical products are explained in detail in the standard, **“ISO 21976 – Packaging – Tamper verification features for medicinal product packaging.”** This standard specifies requirements and provides guidance for the applications, use and check of tamper verification features to the packaging of medicinal products. Any medicinal product organization can refer to and use this standard to introduce any kind of tamper-evident feature in their products

Though tamper-evident labels can be incorporated into medical packaging, there are certain factors, such as sterilization and material compatibility, that need to be considered before finalizing the material of the label. For instance, paper face stock materials with acrylic adhesives are best suited for medical labels. The compatibility of various materials with the respective sterilization modes is presented in the table below.

Table 1: Label materials and their compatibility with different modes of sterilization

Sterilization type	Autoclave	EtO	Irradiation
Sterilizing agent	Steam heat	Ethylene oxide gas	Gamma rays and electron beam
Paper face materials	● ● ●	● ● ●	● ● ●
Filmic PE face materials	Not recommended	Not recommended	● ●
Filmic PP face materials	● ●	Not recommended	Not recommended
Vinyl labels	Not recommended	● ● ●	● ●
Void PET labels	●	● ● ●	● ● ●
Acrylic emulsion adhesives	✓ ✓	✓ ✓	✓ ✓
Acrylic solvent adhesives	✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓
Hot melt rubber adhesives	Not recommended	Not recommended	Not recommended
Solvent rubber adhesives	✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓

On-product marking

This technique facilitates the placement of special images or codes on conventional oral dosage forms.

Complying with regulations - which means provides traceability to the product and preventing counterfeiting, - requires the medical device manufacturing companies to introduce a proper unique code identification marking system, such as with a laser, which has become the preferred means for such systems because of its precision and reliability.



Figure 6 Laser marking system (www.lasersystemseurope.com)

Covert (Simple)

These techniques easily allow brand owners to distinguish genuine from fake products.

The types of covert anti-counterfeiting features include:

Infrared (IR) responsive inks

IR inks are similar to Ultraviolet (UV) inks, with the only difference being that these inks will be visible only to an IR detector. The authenticity can only be identified using special IR pens or IR detectors.



Figure 7 IR responsive ink (www.enyink.com)

Microtext

This feature prints the text at a minimal size, which remains unnoticeable to the naked eye and needs to be magnified to decode the text. This technique is employed in the pharmaceutical packaging industry to avoid counterfeiting.



Figure 8 Microtext printed shelf carton (www.xerox.ca)

Covert (Sophisticated)

These security features are more advanced than basic anti-counterfeiting methods and can be applied to medical device packaging to make counterfeiting significantly more difficult, if not impossible.

Invisible printing

This feature incorporates the use of any special ink or pigment that remains invisible under normal circumstances but can be detected when exposed to specific triggers.

Reactive inks and dyes – These inks react chemically when exposed to agents such as aqueous solutions and solvents. The reaction may result in color changes, staining, smudging, discoloration or any kind of visible sign that indicates an attempt at alteration.

Thermochromic inks/pigments– These inks change color in response to temperature fluctuations, either disappearing or shifting to a different color. Depending on the application, the change can be reversible or irreversible.

Example: Blind spots indicators for vaccines – During the COVID-19 pandemic, Chromatic Technologies Inc. (CTI) developed thermochromic ink technology to address sterility challenges. This technology includes blind spot indicators in vaccine packaging, which are sensitive to temperature fluctuations. The ink changes color if the storage temperature drops below or exceeds the specified limit, signaling potential tampering or improper storage conditions.



Figure 9 Blind spot indicators on vaccines (Source: www.packagingdigest.com)

Forensic

Forensic security features include various types of taggants, such as chemical, DNA, biological, Radio Frequency Identification (RFID) and more.

RFID

In a 2004 report, 'Combating Counterfeit Drugs,' the FDA stated that track-and-trace technologies and product authentication technologies should provide greater drug security. The FDA also added that it is a more recommended solution for ensuring drug legitimacy than current paper records.

Example: RFID Laboratory Phial Label

RFID tag labels are printable and use face stock and adhesive that comply with medical qualifications. These labels can be applied to any test tube or test tube tray, enhancing both security and accuracy in medical applications.



Figure 10 RFID Laboratory Phial Label (www.gaorfid.com)

These labels can be applied to any test tube or test tube tray, enhancing both security and accuracy in medical applications.

In conclusion, covert technologies provides assurance to brand owners, while overt technologies engage consumers in anti-counterfeiting strategies. An ideal counterfeiting protection should be a combination of overt security features with hidden covert technology.

The types of anti-counterfeiting features are not limited to those mentioned above. There are many other features which do exist to provide proper security to the products.

Illustration of the anticounterfeiting methodology

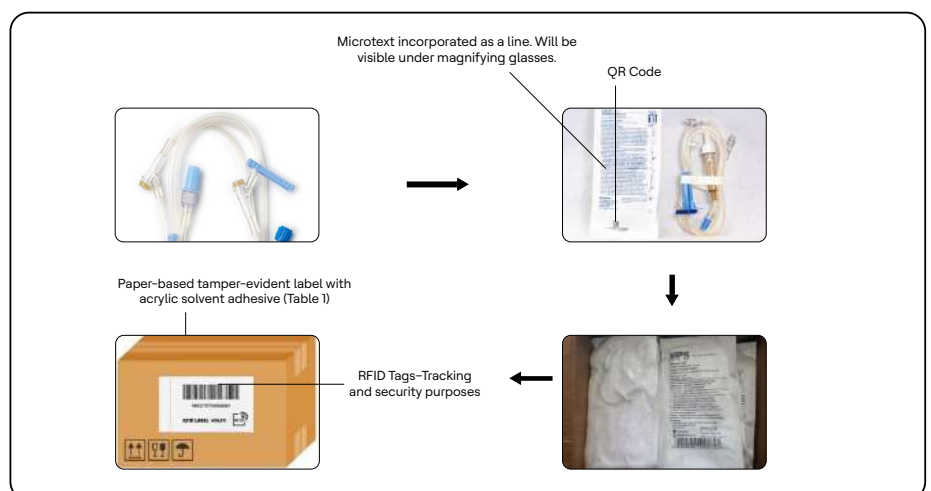


Figure 11 Illustration of the anticounterfeiting methodology

HCLTech capabilities

HCLTech boasts a highly skilled packaging R&D team that offers comprehensive technical support for all packaging solutions. The team comprises SMEs with extensive experience in sustainability, pharmaceuticals and cold chain packaging, among others. With this full-fledged team, HCLTech serves as a one-stop solution for all your medical device packaging requirements.

Conclusion

Based on the above illustration, it can be concluded that the anticounterfeiting features can be incorporated into any desired choice of products. However, it is essential to consider the sterilization methods used, as these can impact the effectiveness of the anticounterfeiting feature, thereby tending to degrade it. Therefore, it is advised to do a deep analysis of the feature and the product chosen along with the sterilization mode to make sure that the feature serves the actual purpose.

In the end, it is up to us to control counterfeiting and make sure that every patient is treated with the right and authentic products.

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