Protecting Patient Safety and Supply Chain Integrity with Advanced Security ICs

With Infineon's OPTIGA™ Authenticate solutions

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Edge ID and Authentication solutions
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Infineon is a leading semiconductor player in the healthcare market

#1

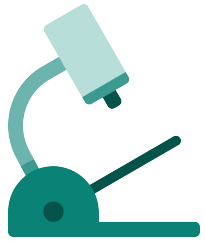
Market position in smart card and security ICs*

4th

Largest supplier of Semiconductors for Healthcare Market**

~58,060

Employees worldwide



71

R&D locations

15

Manufacturing locations

* Excluding NFC controllers & embedded secure element, Source: ABI research, Oct 2023

** Source: Databeans Medical Tracker Q2-2024

Challenges in healthcare disposable security

Counterfeits

Using fake disposables can compromise patient safety and erode trust in the healthcare system.

Unauthorised reuse or refurbishments

Reusing or altering discarded disposables may pose a risk to patient safety and may result in regulatory violations.

Regulatory requirements

To remain compliant and secure, new strategies and early action are required in response to regulations such as the PATCH Act and the EU MDR.

Which of the following types of medical devices are most commonly counterfeited?

a) Surgical instruments
b) Surgical gloves
c) Syringes
d) All of the above

Advanced authentication is crucial for securing the healthcare industry

Securing against counterfeits and unauthorized reuse

cuts down on losses or recalls due to fake products

Authentication solutions improve supply chain integrity

with tamper evidence and traceability for a reliable audit-trail

Versatile product range

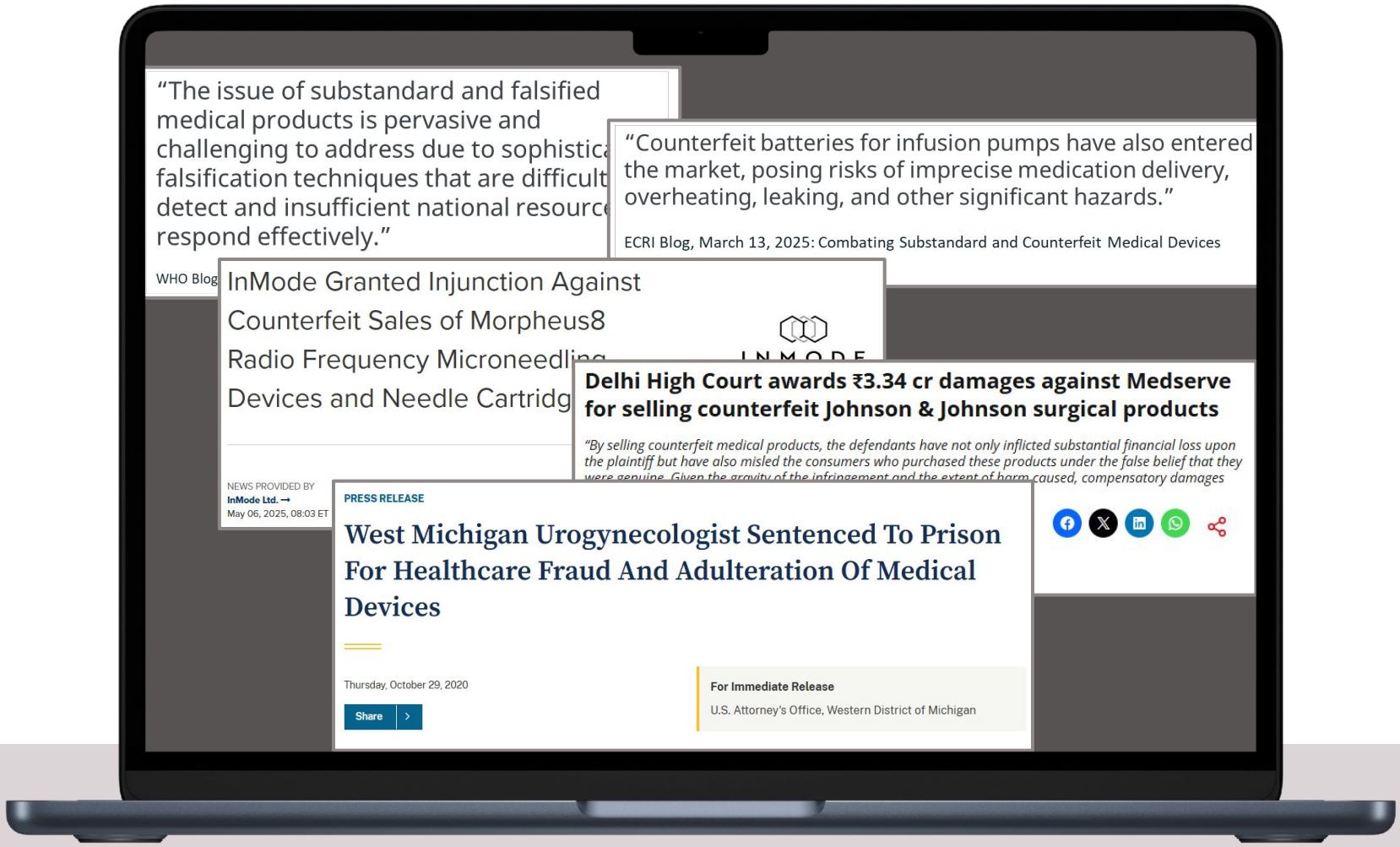
to address interface, memory, sterilization and security requirements

Security expertise to mitigate future cyber security risks

and enable regulatory compliance

The many dangers of counterfeit products

Is this really a problem?



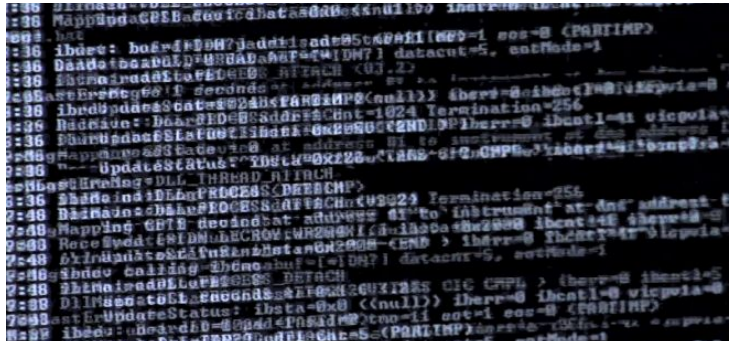
What is the estimated annual sales value of counterfeit or falsified medical devices?

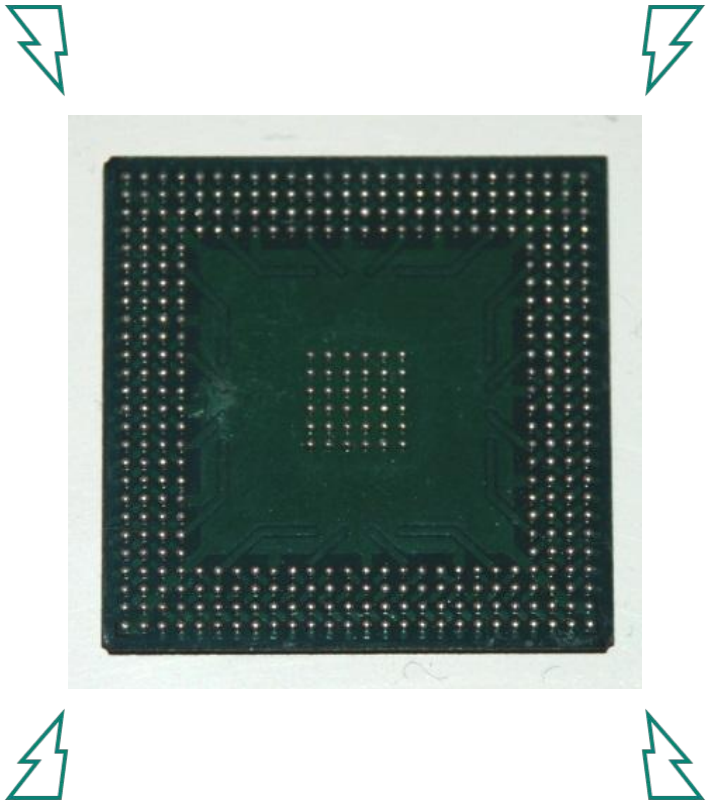
a) $100 million
b) $30 billion
c) $500 billion

How can you decrease the risk of healthcare counterfeits?

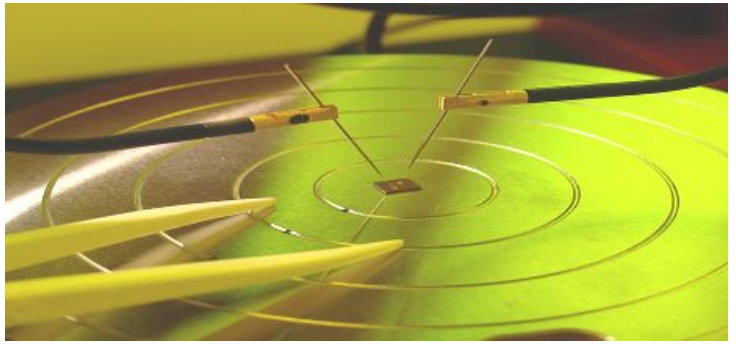
Attack Classification
In the World of Microchips

Logical Attacks
e.g., protocol fuzzing

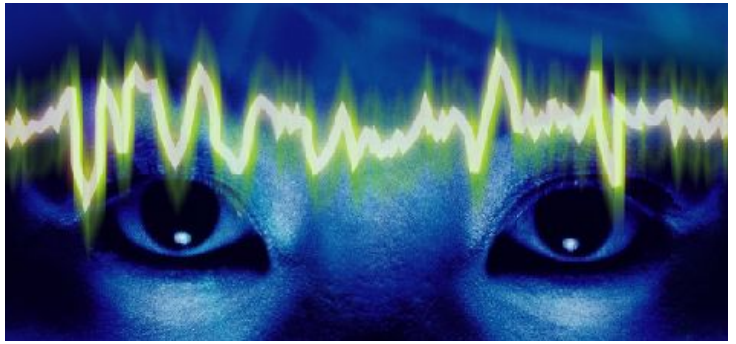




Manipulative Attacks
e.g., probing



Semi-invasive Attacks
e.g., laser fault injection



Observative Attacks
e.g., power analysis

Why hardware-based security?

Future-proof

Protection designed to address both current and emerging security threats

Robust security

More secured, **long-lasting solution** than other measures that are susceptible to bypass

Tailored solutions

Meeting **specific** application needs

Software security is often not enough for device authentication

A successful fight against counterfeits requires advanced measures offered by hardware-based authentication

Security-by-design principles to improve security lifetime

Security-by-design

makes it more time consuming, more expensive and requires significantly more knowledge and equipment to create counterfeits

1

Protection against Reverse Engineering (PRE) is to make physical reverse engineering difficult

2

Smaller technology nodes

3

Hardware mechanisms to protect against tampering and data breaches

4

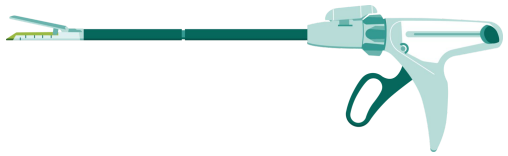
Wafer-level provisioning services

5

Lifecycle management features to prevent reuse

The crucial role authenticators play in mitigating the risk

Healthcare disposables



Surgical tools

OPTIGA™
solutions

Allow manufacturers and users to **check whether consumables are authentic before use,** thereby safeguarding health and brand integrity

Drug delivery devices

Pharma

Contactless (NFC) vs. contact-based (wired) authenticators

How is the device used? | Where is the device placed? | Are there any budget restrictions?

Contactless authenticators

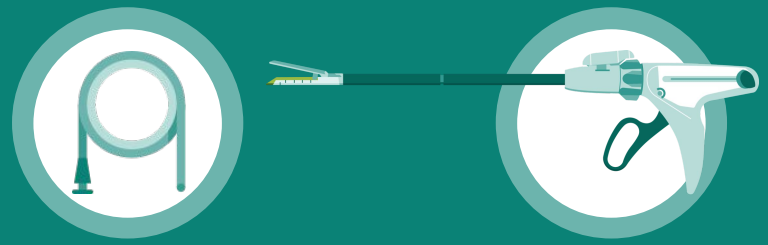
- Liquid environment (subject to spills)
- Vibrations e.g., caused by motors
- Need for frequent consumable replacement
- Verify consumable using smartphone/reader

Contact-based authenticators

- Ease of integration to existing wired infrastructure
- Cost-effective solution
- Less distance constraints in comparison to NFC

Typical use cases

Authentication of disposables



Catheters

Stapler cartridge

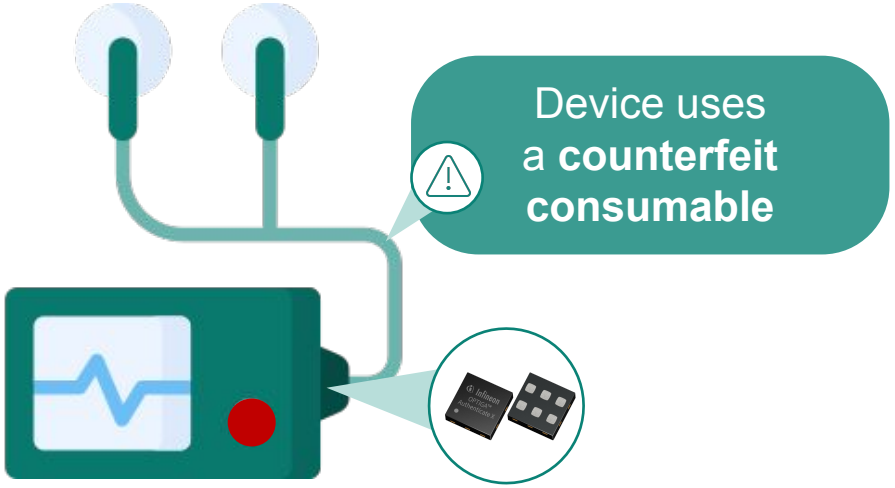
Connected electronic devices

Sensors

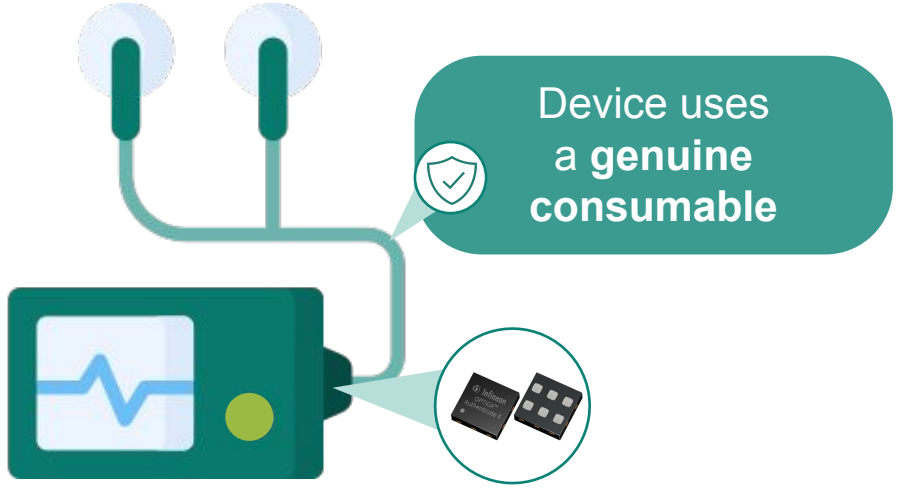
TRUE or FALSE

Counterfeit medical devices are usually easily detected due to poor manufacturing quality

Case study 1:
Authenticating consumables with OPTIGA™ Authenticate X



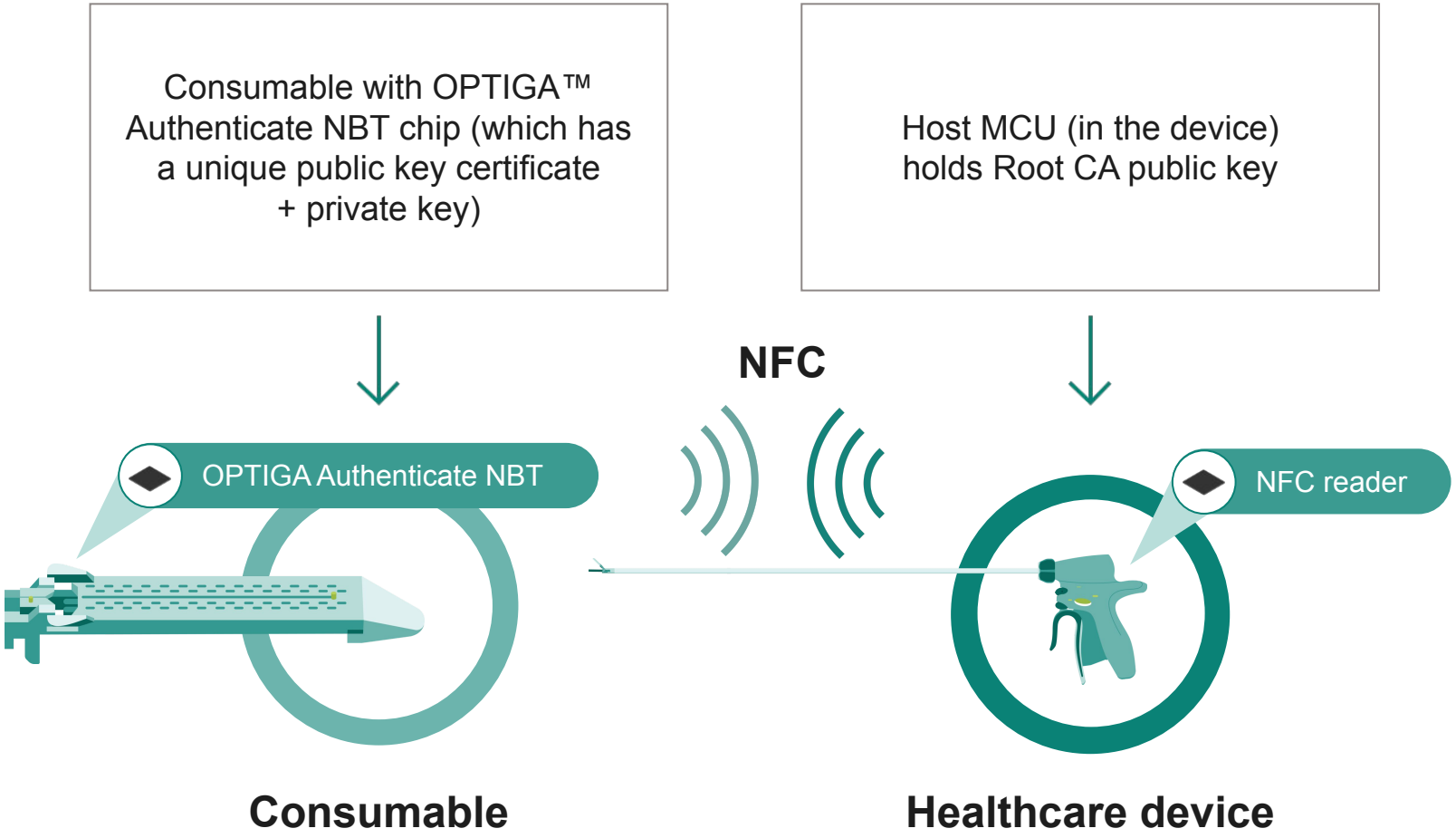
Monitoring sensor
with a **counterfeit** cable



Monitoring sensor
with a **genuine** cable

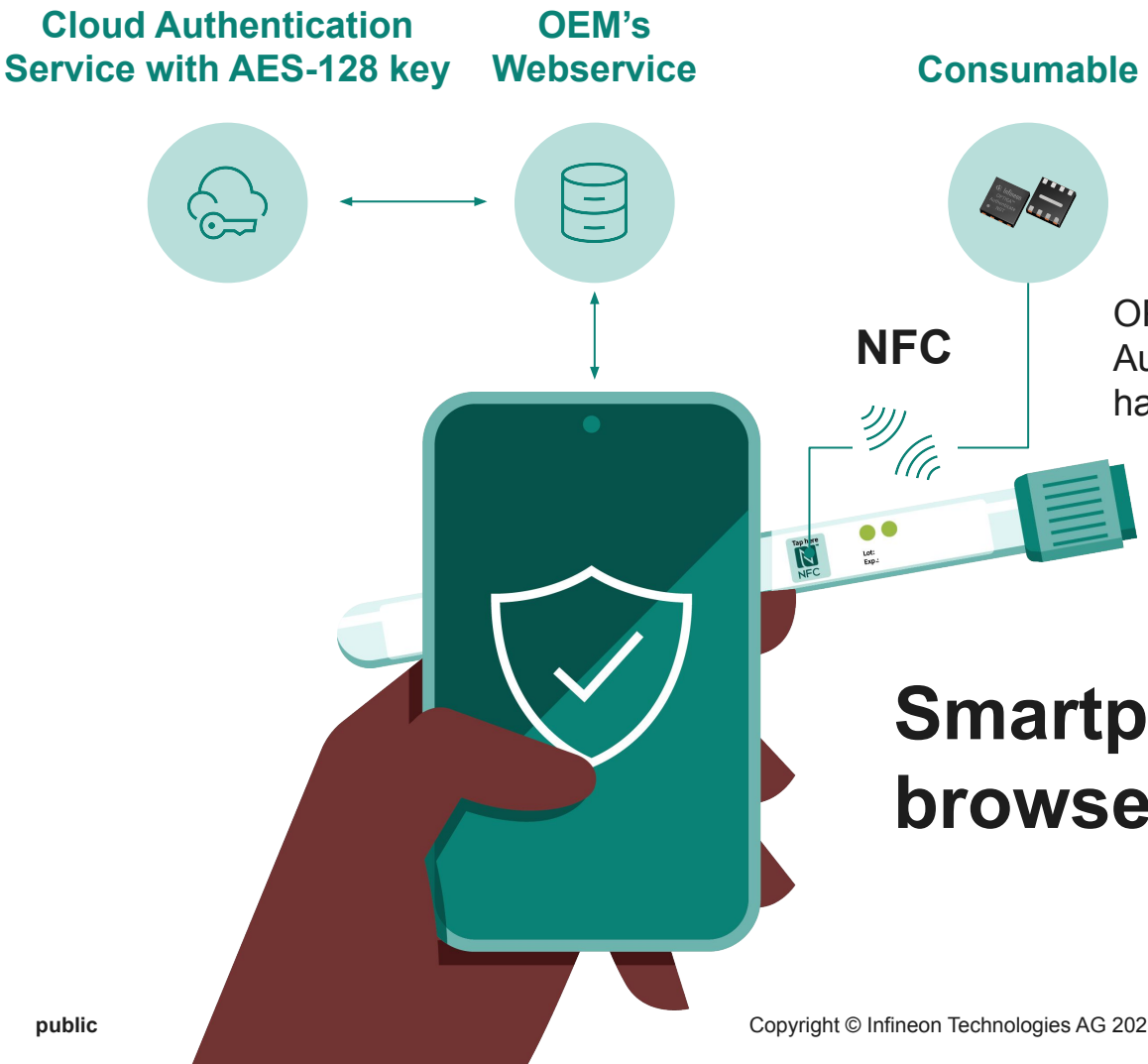
Case study 2

Offline authentication of consumables using OPTIGA™ Authenticate NBT



Case study 3

Authentication of consumables using OPTIGA™ Authenticate NBT and a smart phone

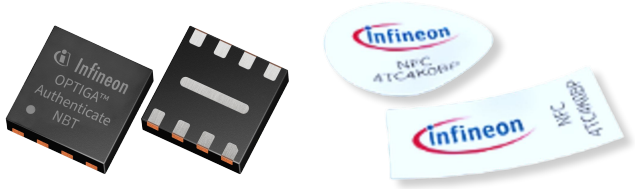


OPTIGA™ Authenticate solutions for healthcare applications

OPTIGA™ Authenticate

Contactless (NFC)

Secured NFC Tag
OPTIGA™ Authenticate NBT
- NFC-I2C (USON 8)
- NFC (bare die)

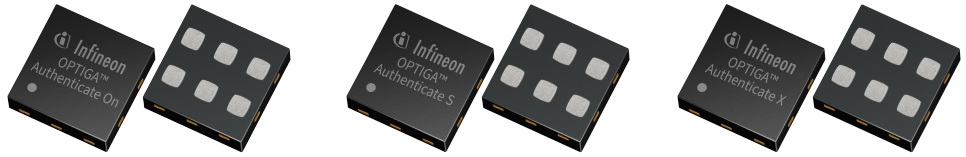


Custom

For applications requiring unique designs not addressed by our standard offering

Contact-based (Wired)

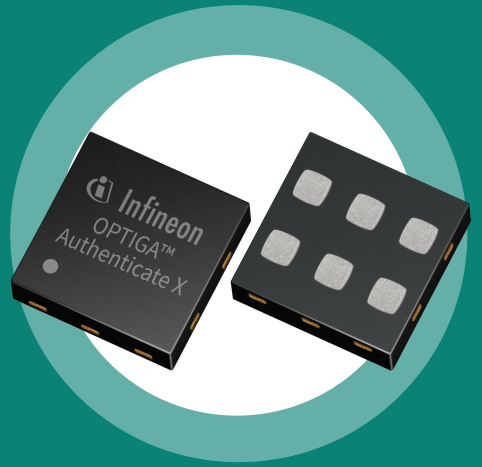
OPTIGA™ Authenticate S
OPTIGA™ Authenticate ON
OPTIGA™ Authenticate X[1]



[1] Roadmap product

Cutting-edge technologies for unmatched brand security

- Optimal solution with NFC-based/wired products
- Superior anti-counterfeiting solutions
- Well-established partner ecosystem
- Sterilization-ready products
- Support for custom & tailored implementations
- Trusted expertise and support
- Long-term trustworthy sourcing



Why choose Infineon's authenticators?

Infineon provides the highest quality and reliability for Security and Smartcard Solutions

Top level outgoing quality
Based on Infineon caused defects per millions and customer quality surveys in last 5 years

High customer satisfaction
Quality >90% at customer surveys in last 5 years

Global quality management
Strong regional dedicated customer support

Stable productions
100% fulfillment of committed stability parameters in development, front end, back end

100% Certified
ISO 9001, IATF 16949, CQM Mastercard, CC, …

We deliver what we promise. That's Infineon quality.

Disclaimer for critical applications

It is the customers responsibility to carefully assess whether the Infineon products fulfill the requirements of their application.

Infineon Technologies points out that the Infineon products are not specifically designed and tested for use in medical applications.


Infineon