World Health Organisation (WHO) Patient Safety Day

The Role of the Notified & Approved Body

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2024-09-17

World Health Organization – Patient Safety Day.

Founded in 1948, WHO is the United Nations agency that connects nations, partners and people to promote health, keep the world safe and serve the vulnerable – so everyone, everywhere can attain the highest level of health.

https://www.who.int/about

World Health Organization – Patient Safety Day.

What is Patient Safety Day?

The World Health Organization's (WHO) World Patient Safety Day encourages global and national health organisations as well as patients, families, health workers and health care leaders to show their commitment to patient safety

What is the purpose of this BSI Webinar?

British Standards Institution (BSI) is involved in the regulation (certifying) of medical devices across the world. As part of the WHO Patient Safety Day, we want to show our commitment to ensure patients and healthcare professionals are aware of our involvement in ensuring patient safety is held to the highest standards.

Poll Question:
Which of these best describes your background?

A- Healthcare Professional

B- Medical Device user/recipient (patient)

C- Regulatory affairs professional – Manufacturer

D- Regulator/Competent Authority

E- Other

There are over 500,000 medical devices available to patients in Europe

In comparison, there are around <100,000 registered medicines in Europe.

Medical devices play an important role in our European healthcare system, ensuring that we are able to diagnose and treat patients for the many medical conditions that exist.

The European Commission is responsible for creating laws on medical devices in the European Union. These laws are often referred to as regulations.

Europe has the Medical Device Regulation 2017/745 and In-Vitro Medical Device Regulation 2017/746

The British Government is responsible for creating laws on medical devices in the UK .

The United Kingdom has the Medical Device Regulation 2002

The Importance of Regulation

Regulation: a rule or order issued by an executive authority or regulatory agency of a government and having the force of law.

Oxford Dictionary

The Importance of Regulation

- Regulations can help ensure that there is a minimum level of safety to abide by.
- Regulations can ensure that the public and the environment are protected against dangerous practices.
- Regulations help to ensure that controls are in place for industries who are involved in complex or high-risk activities.
- Regulations may develop further in reaction to serious incidents and public threats

Monitoring of safety practices and ethics needed

09 June 2010

BP says the accident was caused by the failure of eight different safety systems that were meant to prevent this kind of incident:

Dodgy cement

Valve failure

Pressure test misinterpreted

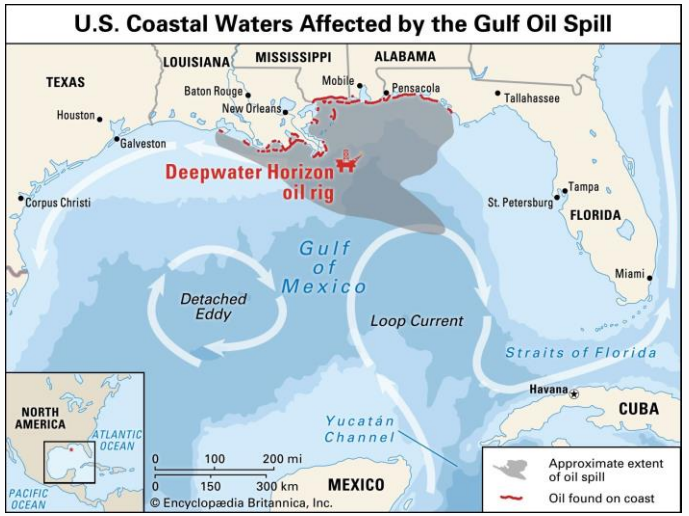
Leak not spotted soon enough

Valve failure no. 2

Overwhelmed separator

No gas alarm

No battery for Blow Out Preventor



Flawed analysis, failed oversight –

21 March 2019

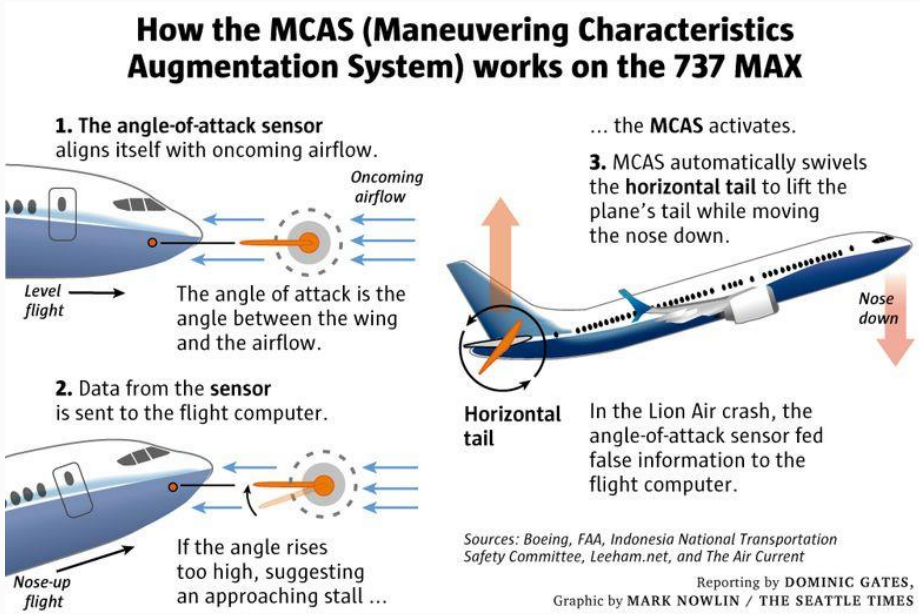
Delegated to Boeing

The FAA, citing lack of funding and resources, has over the years delegated increasing authority to Boeing to take on more of the work of certifying the safety of its own airplanes.

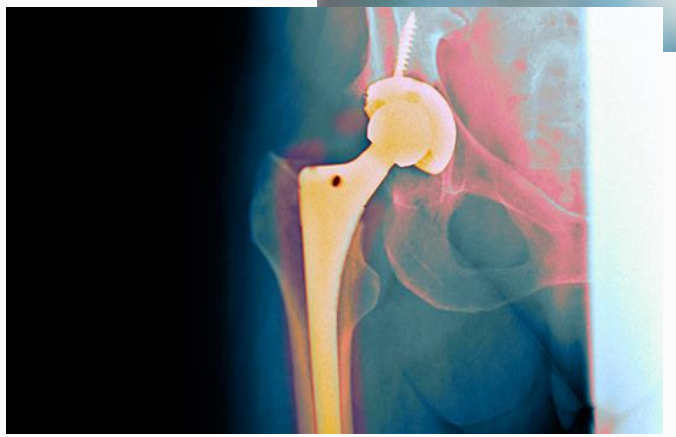
Early on in certification of the 737 MAX, the FAA safety engineering team divided up the technical assessments that would be delegated to Boeing versus those they considered more critical and would be retained within the FAA.

"There wasn't a complete and proper review of the documents," the former engineer added. "Review was rushed to reach certain certification dates."

BOEING®



What is considered a medical device?



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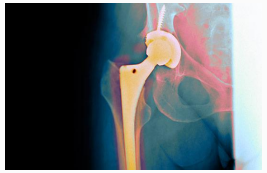
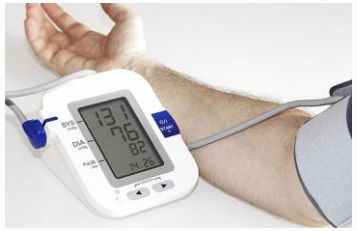


The regulations define what is considered a medical device. There are very strict rules around what qualifies something as a medical device and when something is considered a medicine.



Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

What is an approved or notified body?

An approved or notified body is responsible for reviewing medical devices before they are released. The approved and notified body issue certificates to manufacturers of medical devices once they have passed the regulatory process and have proven they meet the strict requirements of the law.

What is an approved or notified body?

An approved or notified body is also responsible for ensuring that medical device manufacturers follow the strict requirements of the law after they are released on the market.

British Standards Institute (BSI) is both an approved and notified body.

What the difference between an Approved and Notified Body?

An Approved Body is responsible for approving medical devices in the UK.

This symbol is placed on medical devices that have been approved for the UK.

What the difference between approved and notified?

A Notified Body is responsible for approving medical devices in the European Union.

This symbol is placed on medical devices that have been approved for the European Union.

What the difference between approved and notified?

CE 2797

There may be a number after the CE marking symbol to demonstrate which notified body approved the device. Each number is unique to a notified body.

How does a notified body become registered?

A. Active devices

1. *Active implantable devices*

MDA CODE	Active implantable devices
MDA 0101	Active implantable devices for stimulation/inhibition/monitoring
MDA 0102	Active implantable devices delivering drugs or other substances
MDA 0103	Active implantable devices supporting or replacing organ functions
MDA 0104	Active implantable devices utilising radiation and other active implantable devices

- Notified Bodies are designated (approved) by a Competent Authority (Government) of a member state in the EU.

- The notified body is designated (approved) to these codes through a rigorous assessment of the competency of the individuals employed by the notified body.

How do approved or notified bodies ensure devices remain safe for us?

Approved and Notified bodies are required to visit manufacturing sites to ensure that they are following the strict aspects of the regulation.

We check to ensure that:

- The devices being manufactured are of a consistent high quality.
- The sterile areas are sufficiently clean enough to make devices.
- Manufacturers are monitoring and responding to complaints

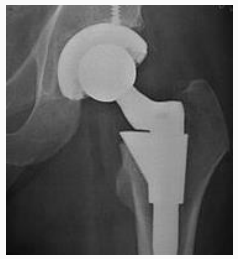
How do approved or notified bodies ensure devices remain safe for us?

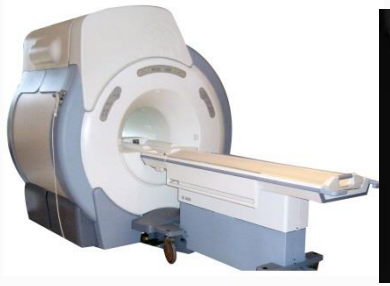
Prior to approval of the medical device, the approved and notified body is required to review 1000’s of pages of the manufacturer's documentation ensuring that:

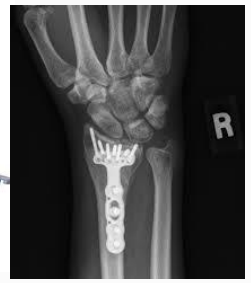
- The design of the device is safe and effective
- Clinical data is reviewed including clinical studies.
- The manufacturer has an effective process in place to continue to monitor the devices once released.

Manufacturers must be able to demonstrate that they are better than or equal to what is currently available. Sub-standard products will not be approved.

Classification of Medical Devices .







Class III

Class IIb

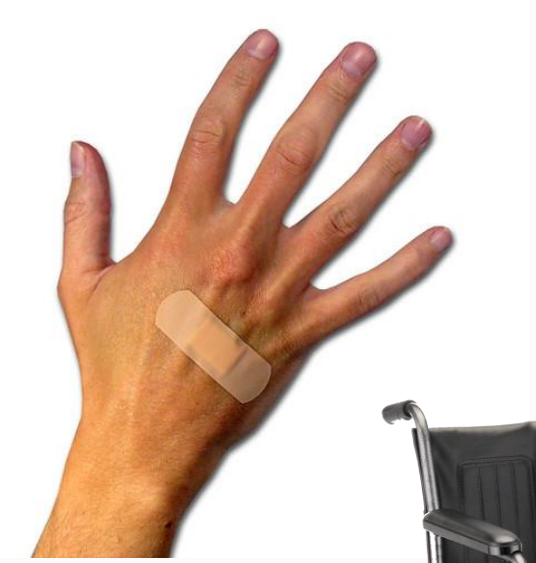
Class IIa

Class I

RISK, DURATION, INVASIVENESS

- The Regulations are built on a risk-based approach and medical devices are classified according to risk.
- Class I is the lowest risk classification.
- Class III is the highest risk classification.

What types of devices does an approved or notified body certify?

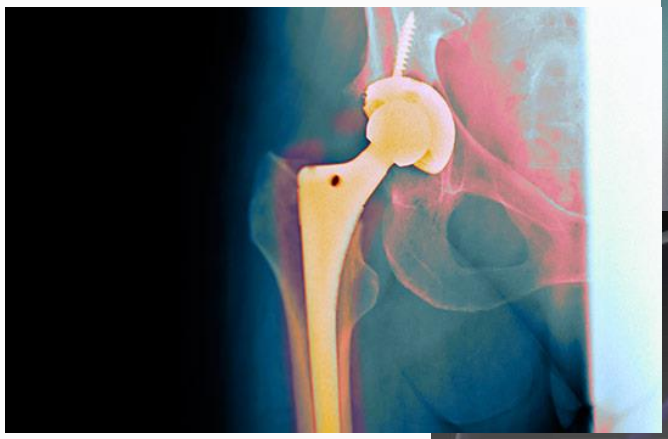


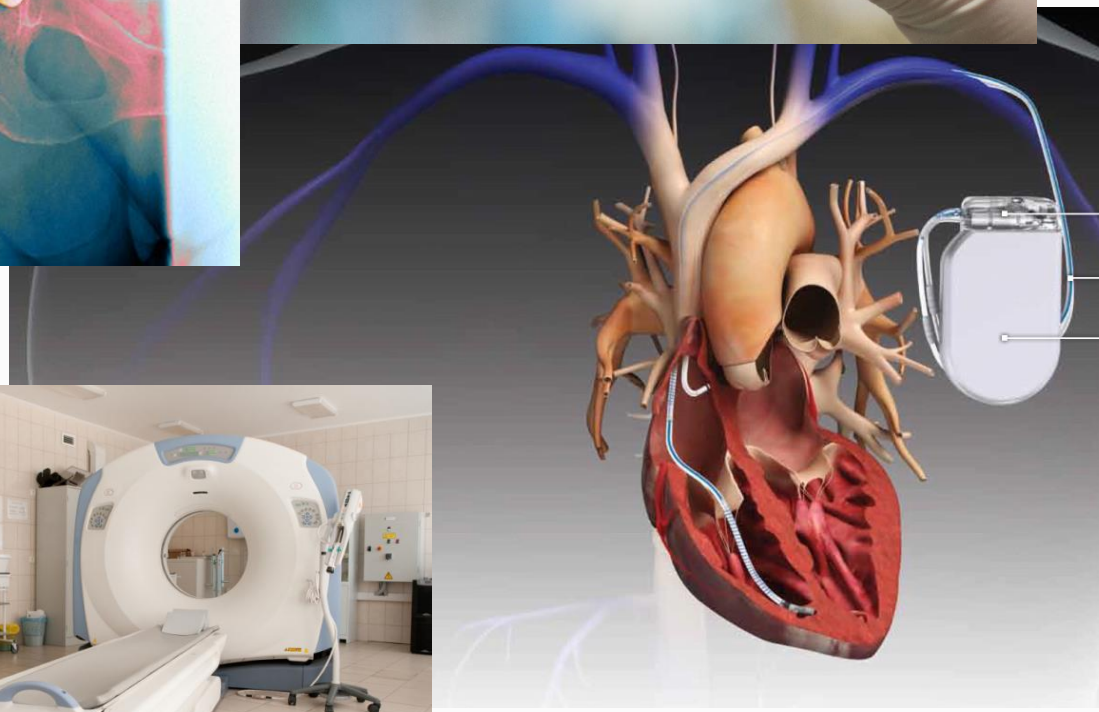
Low risk devices (Class I devices) can be self-certified by a manufacturer with oversight from the government.

Approved/Notified bodies are not usually involved with these devices.

What types of devices does an approved or notified body certify?

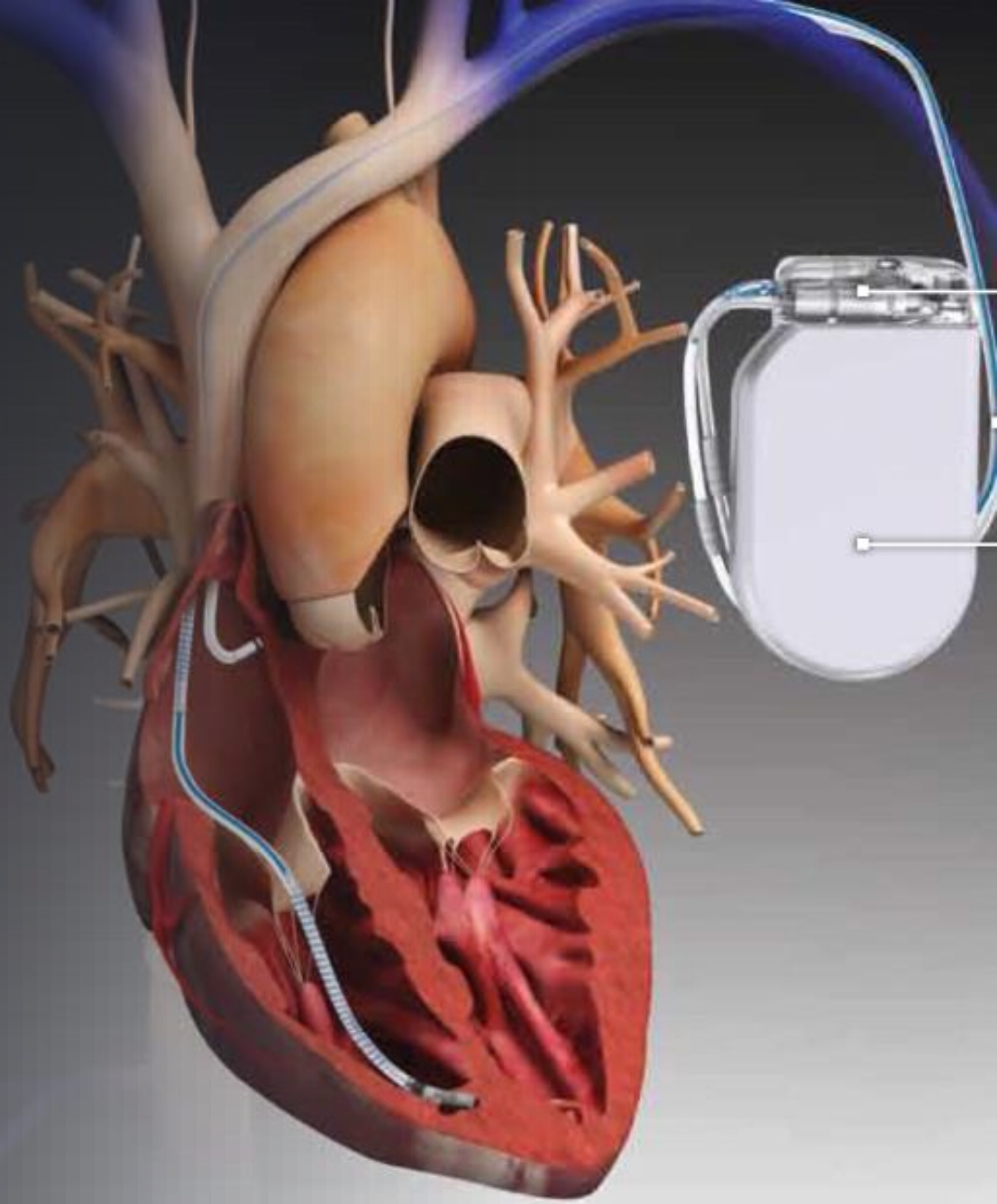
High risk devices (Class IIa, IIb, and III devices) are certified by an approved or notified body.





Who is involved in the Notified Body/Approved Body assessment?

- Let's take this example of a pacemaker and lead that may be used for a patient with a slow heart rate.



Poll Question:
How many different people are involved in a NB/AB medical device assessment?

A: 1-2

B: 3-5

C: 6-10

D: 11+

Poll Answer:

How many different people are involved in a NB/AB medical device assessment?

A: 1-2

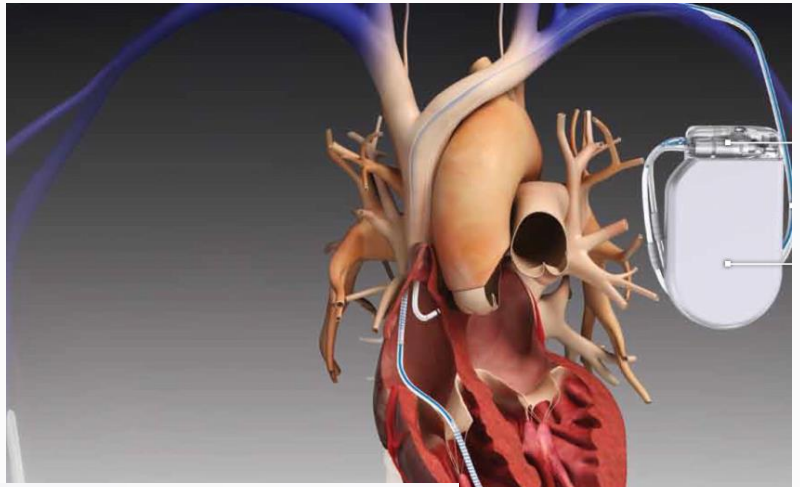
B: 3-5

C: 6-10

D: 11+

Who is involved in the Notified Body/Approved Body assessment?

A clinician is employed to evaluate the clinical data held on the device and the benefit-risk assessment.



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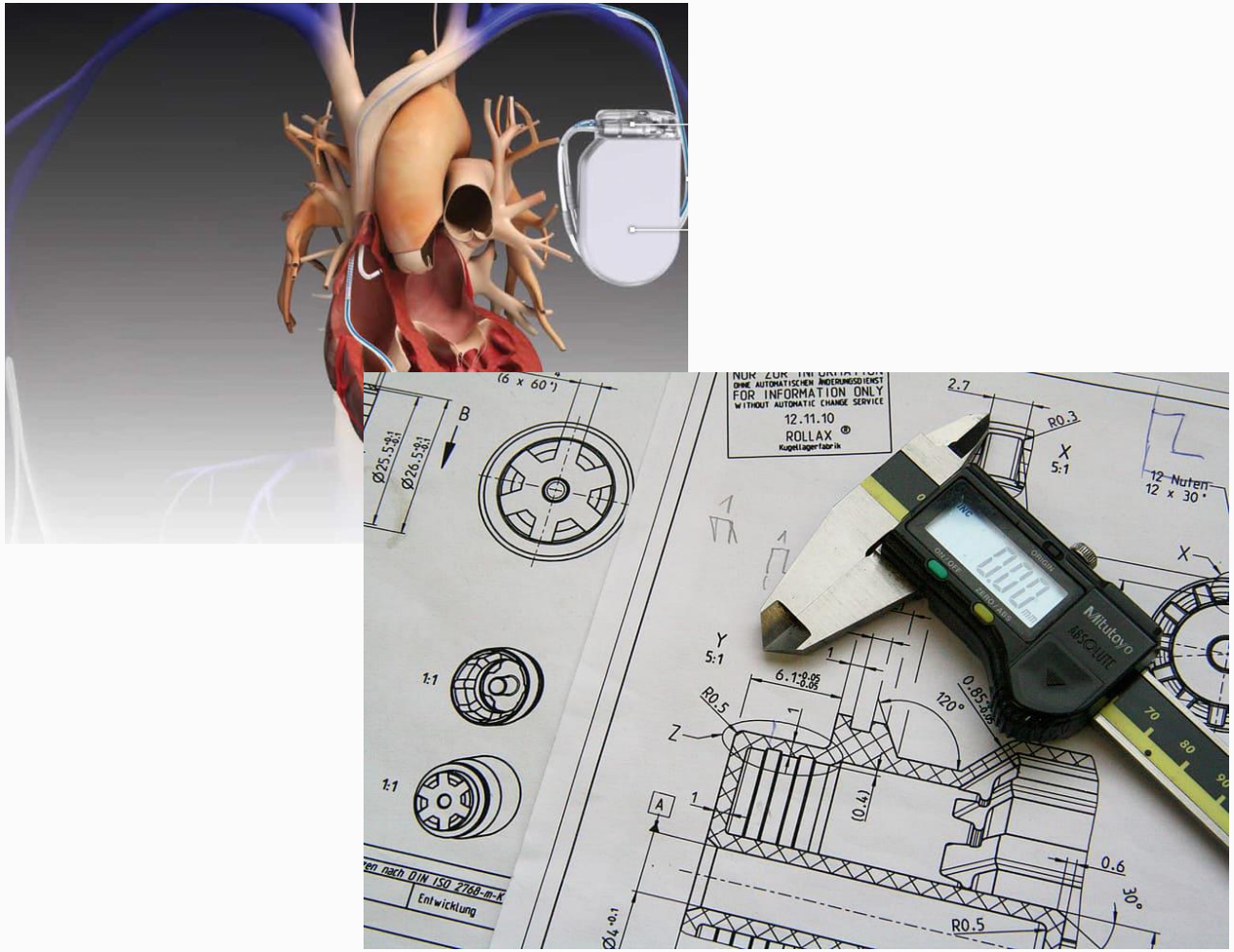
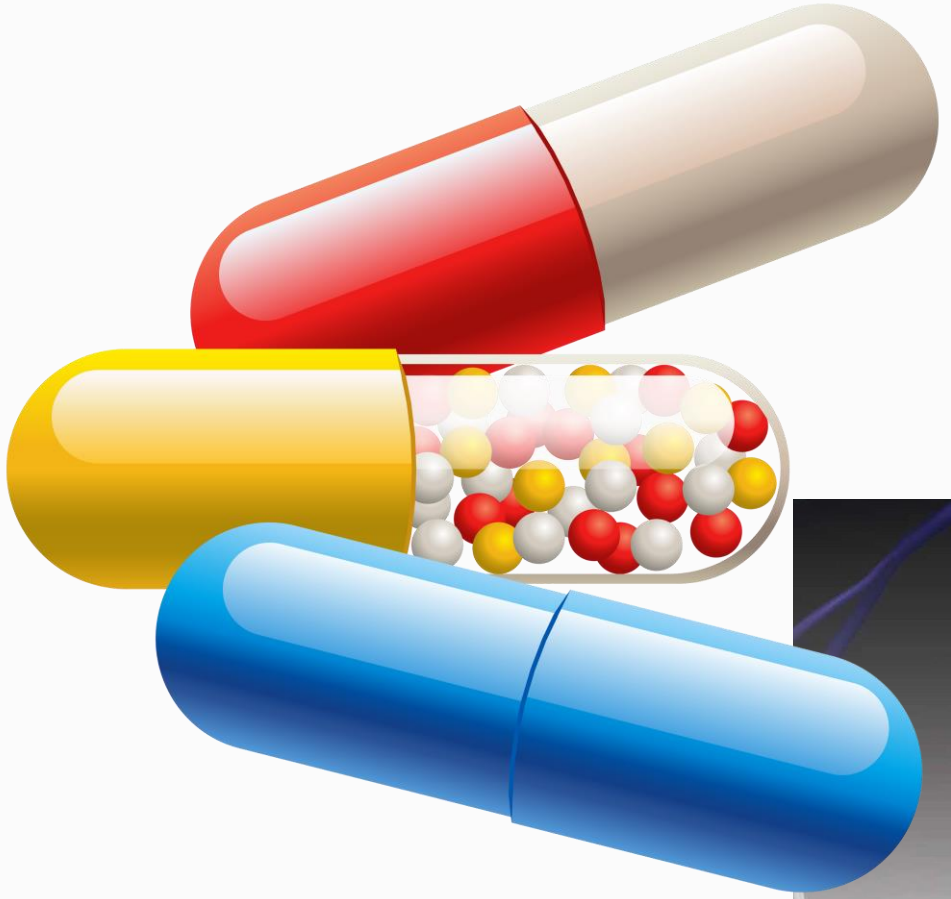
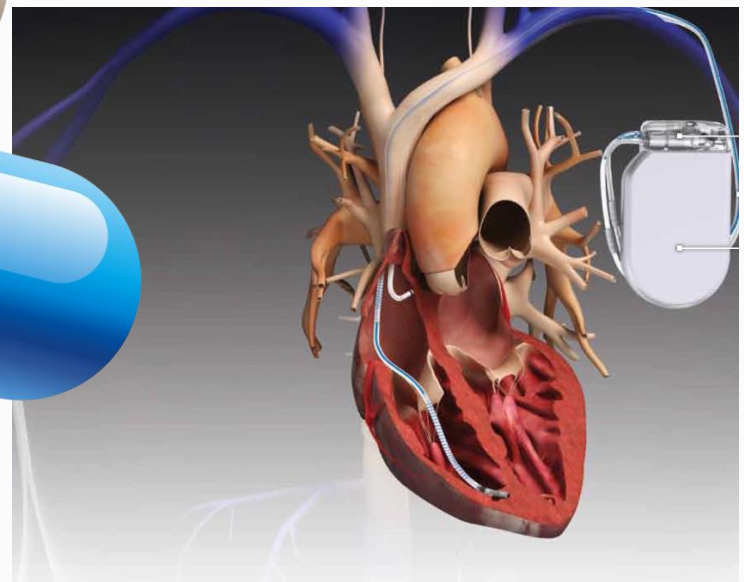


Technical expert is employed to assess the technical specifications to standards (ISO5841) and review the bench (laboratory) testing reports provided by the manufacturer .

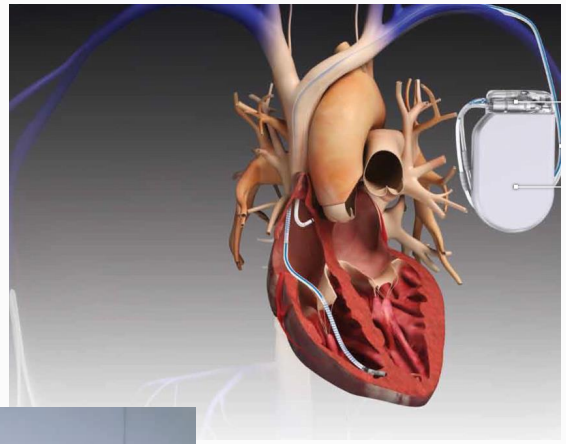
Who is involved in the Notified Body/Approved Body assessment?

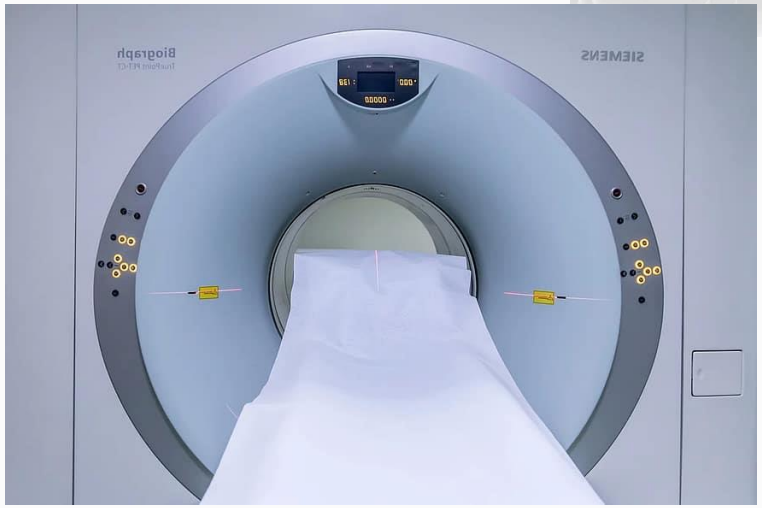




A medicinal expert (pharmacist) is employed to evaluate the impact of any medicinal substances. (E.g. dexamethasone.)

Who is involved in the Notified Body/Approved Body assessment?

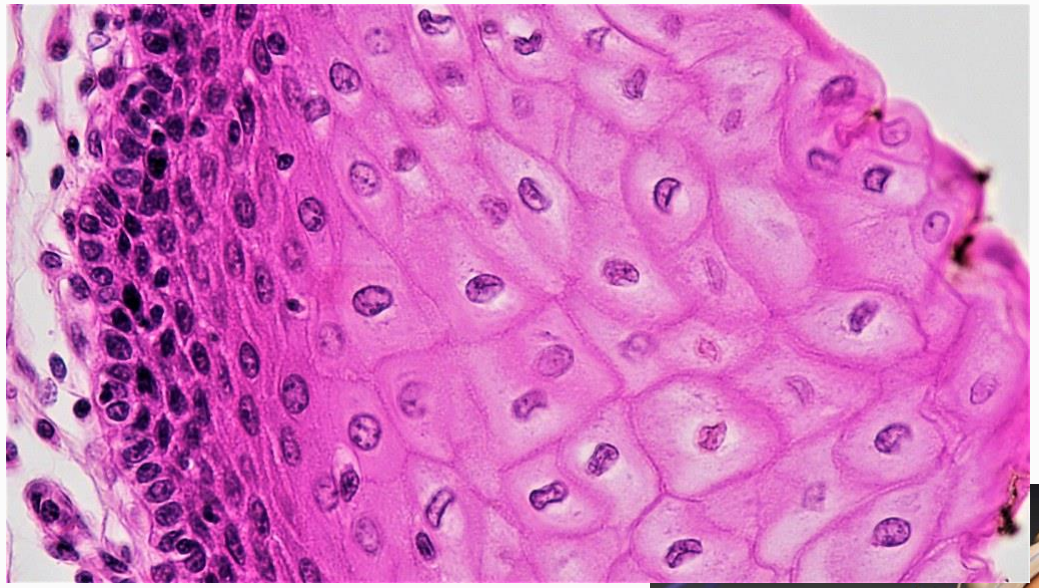




An MRI Technical expert is also employed to ensure the medical device safe enough for an Magnetitic Resonance Imaging (MRI) Scanner

Who is involved in the Notified Body/Approved Body assessment?

Biocompatibility experts are employed to assess exposure and compatibility/degradation of materials in the human body and that the device is biologically safe.



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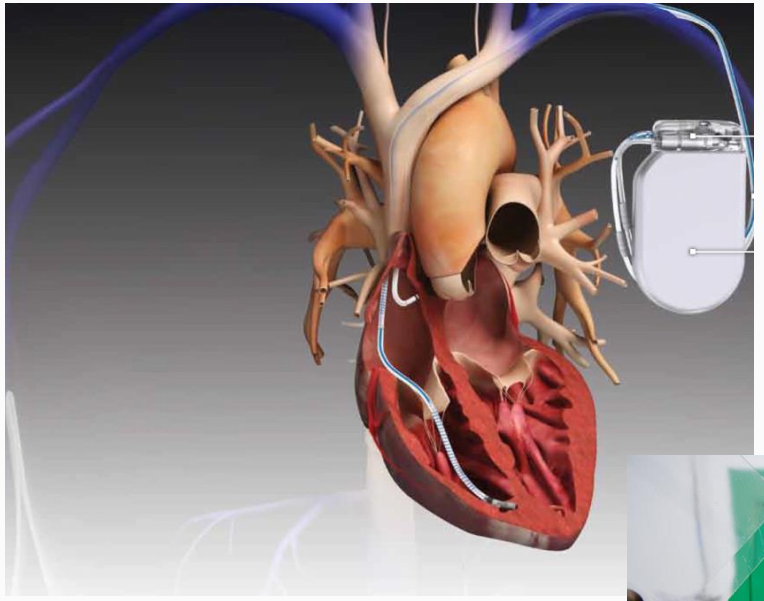
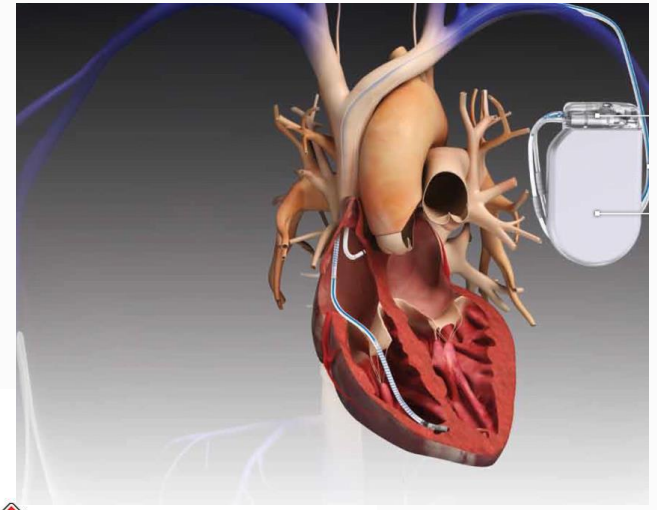


Microbiologists ensure the manufacturer has sterilised the devices effectively to prevent infections.

Who is involved in the Notified Body/Approved Body assessment?

Packaging of the device is reviewed to ensure it protects the product during delivery to the hospital and that the device is labelled correctly.



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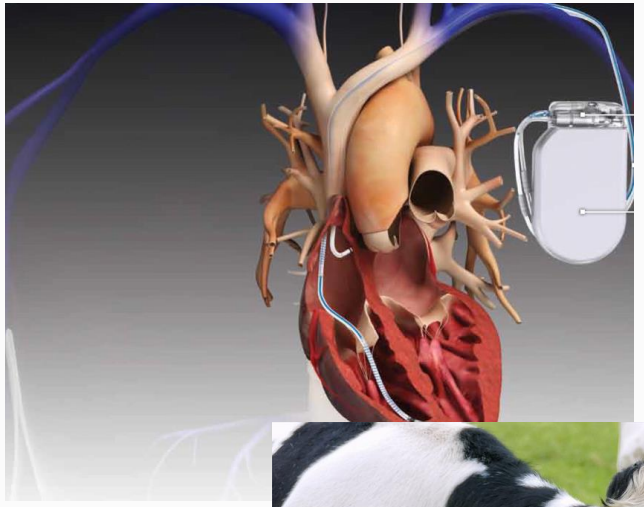
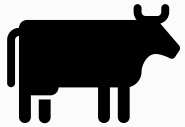
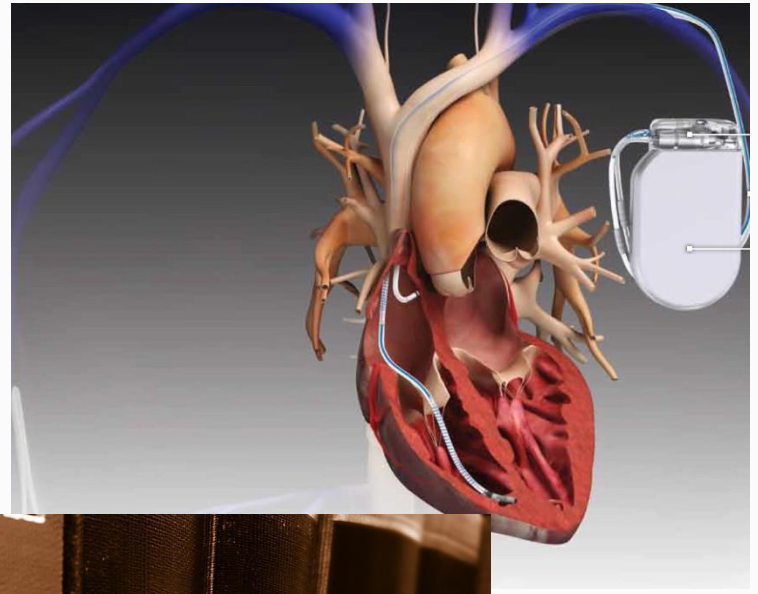


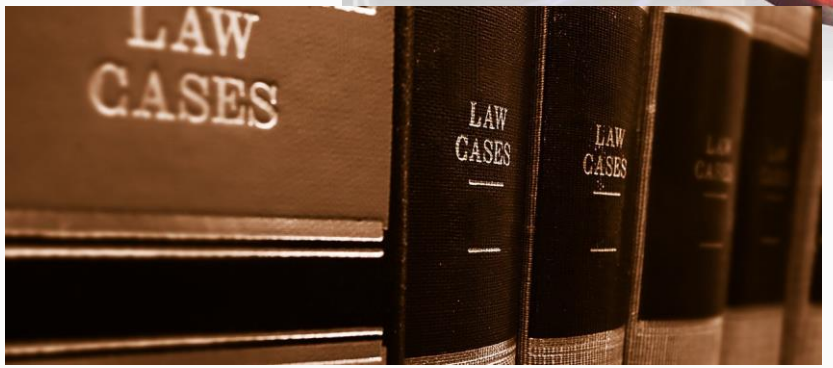


Animal tissue experts assess impact and safety of the use of animal products either in the device or used in the manufacturing process.

Who is involved in the Notified Body/Approved Body assessment?

Scheme Manger (Legal Expert) to recommend certification and ensure process is organised/manufacturer is informed.





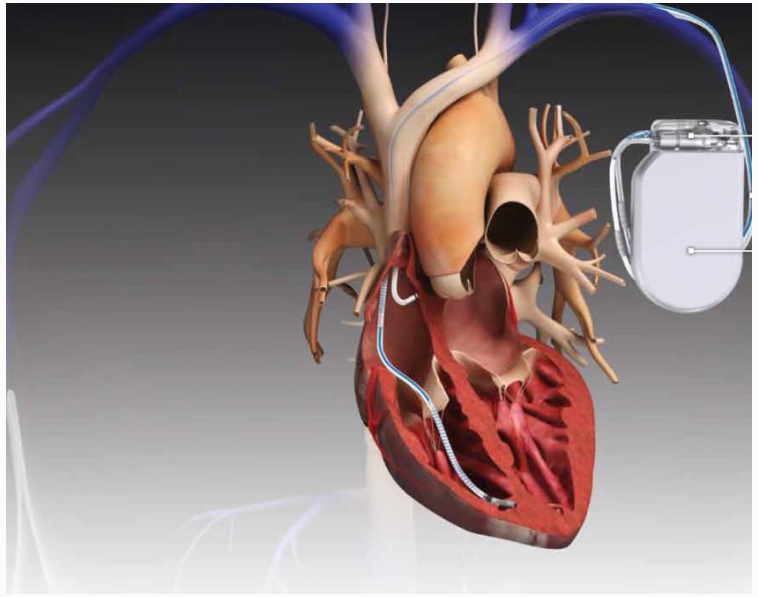
Who is involved in the Notified Body/Approved Body assessment?

A clinician is employed to employed to evaluate the clinical data held on the device and benefit-risk assessment.

A medicinal expert (pharmacist) is employed to evaluate the impact of any substances. (E.g. dexamethasone.)

An MRI Technical expert is also employed to evaluate any potential issues associated with claims of MRI Conditionality.

Biocompatibility experts are employed to assess exposure and compatibility/degradation of materials in the human body.



Scheme Manger (Legal Expert) to recommend certification and ensure process is organised/manufacturer is informed.

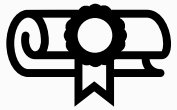
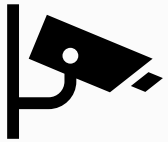
Technical expert is employed to assess the technical specifications to standards (ISO5841) and review pre-clinical data such as bench testing, ageing tests.

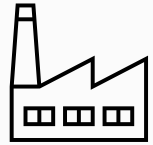
Microbiologists employed to assess sterility methods.

Packaging and transit tests are reviewed by a technical expert including labelling requirements.

Animal tissue experts assess impact of the use of animal by-products either in the device or used in the manufacturing process.

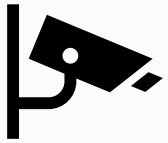
What happens after a medical device is certified?

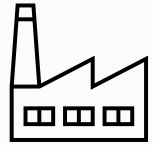



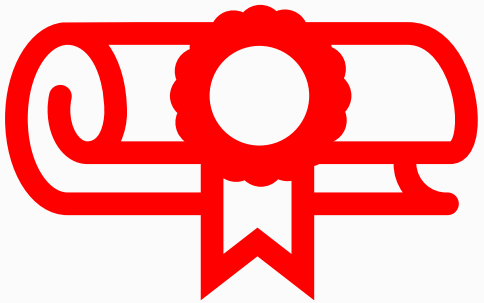


After a medical device is certified, the manufacturer, notified body/approved body have legal requirements to ensure that the devices are monitored to ensure that they continue to be safe to use and are effective for the patients who receive them.

What happens after a medical device is certified?



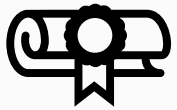


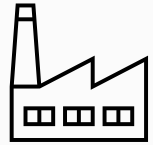


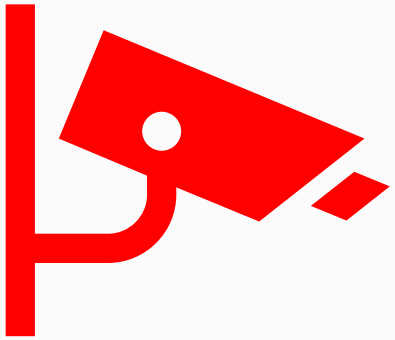
Certificates are usually valid for 5 years.

When the certificate expires, the manufacturer is required to reapply for a certificate and the approved/notified body will review its safety again.

What happens after a medical device is certified?

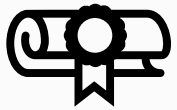


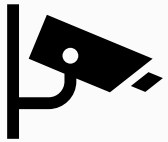


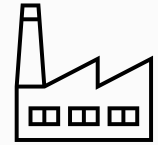


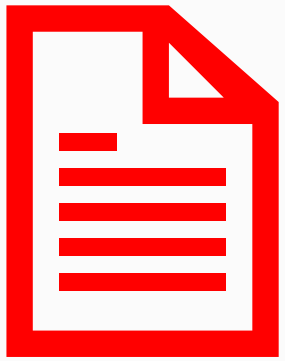
The manufacturer must monitor the device for complaints or problems and report any serious harm to both the approved and notified body and the competent (government) authorities.

What happens after a medical device is certified?





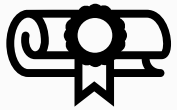


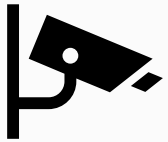


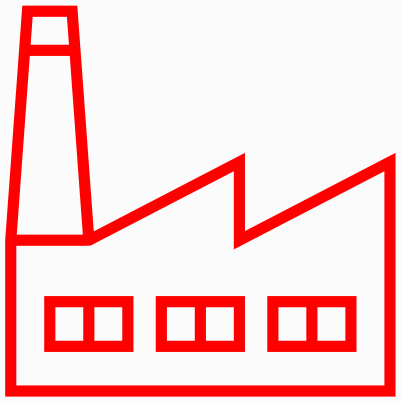
Complaints, serious harm to patients and any new clinical data from studies and other activities are reported in a Periodic Safety Update Report (PSUR) which is evaluated by the Approved/Notified Body.

Any concerns can result in the certificate being suspended and/or cancelled, meaning the device can no longer be available for patients.

What happens after a medical device is certified?







The Notified body is legally required to perform an unannounced visit at either the manufacturers premises or to one of the critical suppliers/subcontractors at least once every five years.

Spontaneous checks can help ensure no corrupt activity is being committed.

Committed to Safety

- We all rely on access to safe and effective medical devices.
- Approved and Notified bodies are committed to ensuring safety of the devices for these patients through our everyday activities.
- We hope this webinar has been helpful and beneficial in helping you understand the rigorous processes that are in place to keep you safe.

The BSI Patient & Healthcare Professional Partnership Programme.

- The Patient and Healthcare Professional Partnership programme will launch in 2025.
- The aim of this programme is to ensure that patients and healthcare professionals have a voice in the decisions we make.
- It will be an opportunity for patients and healthcare professionals to learn about the work we do and for BSI to listen to feedback from our patients and healthcare professionals about their concerns with medical devices.
- More information will follow next year.

Thank You