Medical Devices and the EU regulation

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BME Education

X-Ray Medical Image Reconstruction and Simulation

Biomedical Instrumentation and measurements

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RESEARCH INSTITUTES, UNIVERSITIES

INDEPENDENT ORGANISATIONS – WHO

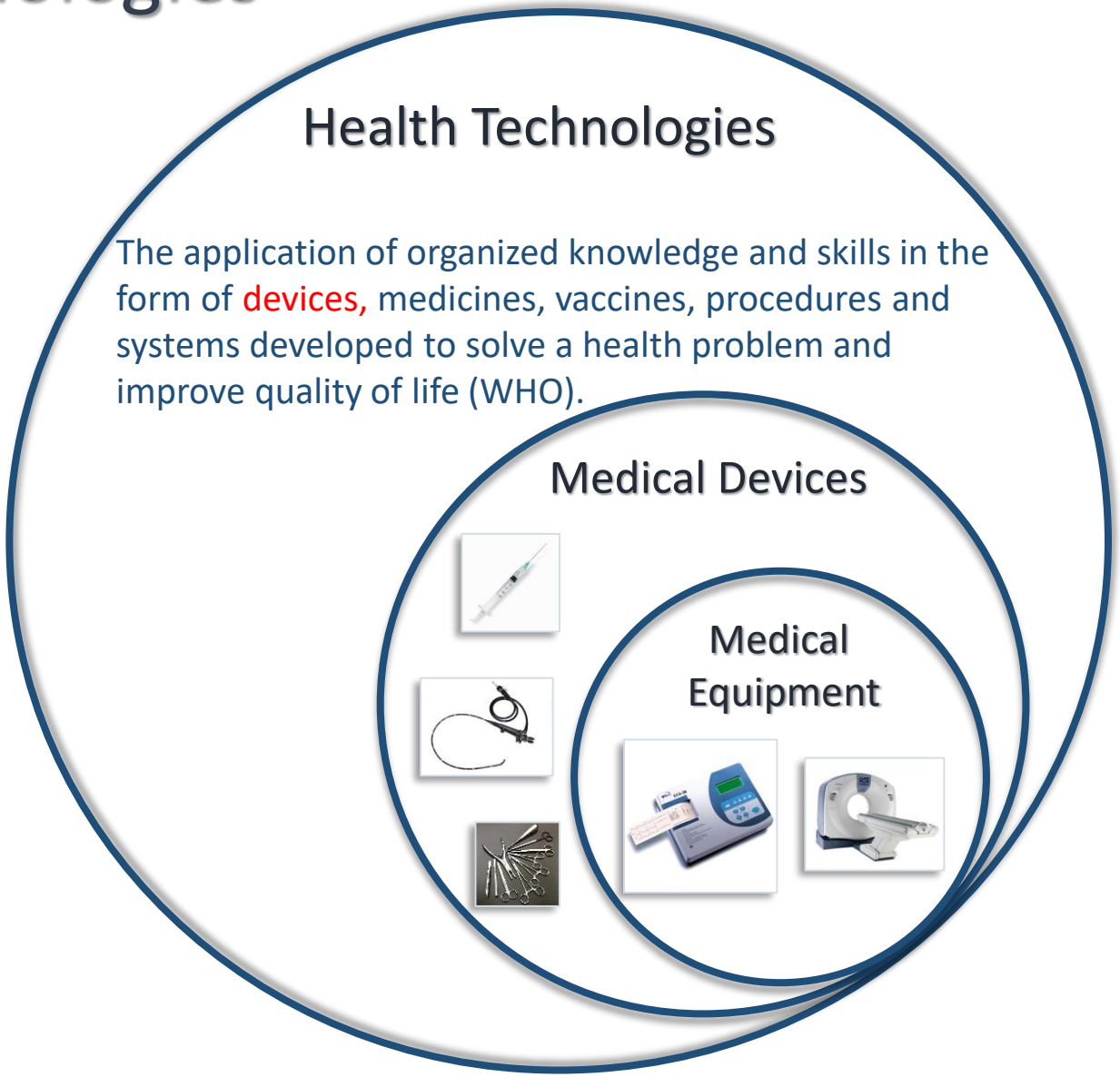
COMPETENT AUTHORITIES, NOTIFIED BODIES

MDs MANUFACTURERS

DECISION MAKERS – HEALTH CARE SYSTEMS

HOSPITALS - PATIENTS

Health Technologies



The Medical Device Industry Today

The global medical device market is estimated to be more than 300 Billion Euros in year 2016, with more than 500,000 medical technologies registered.

Medical technology industry is one of Europe's most diverse and innovative high-tech sectors, with 26,000 medical technology companies that provide over 650,000 jobs in Europe.

Covers almost **1/3** of the world production

€110B

12,400 patents are registered in 2016 in Europe

DEFINITION AND DIVERSITY OF MEDICAL DEVICES

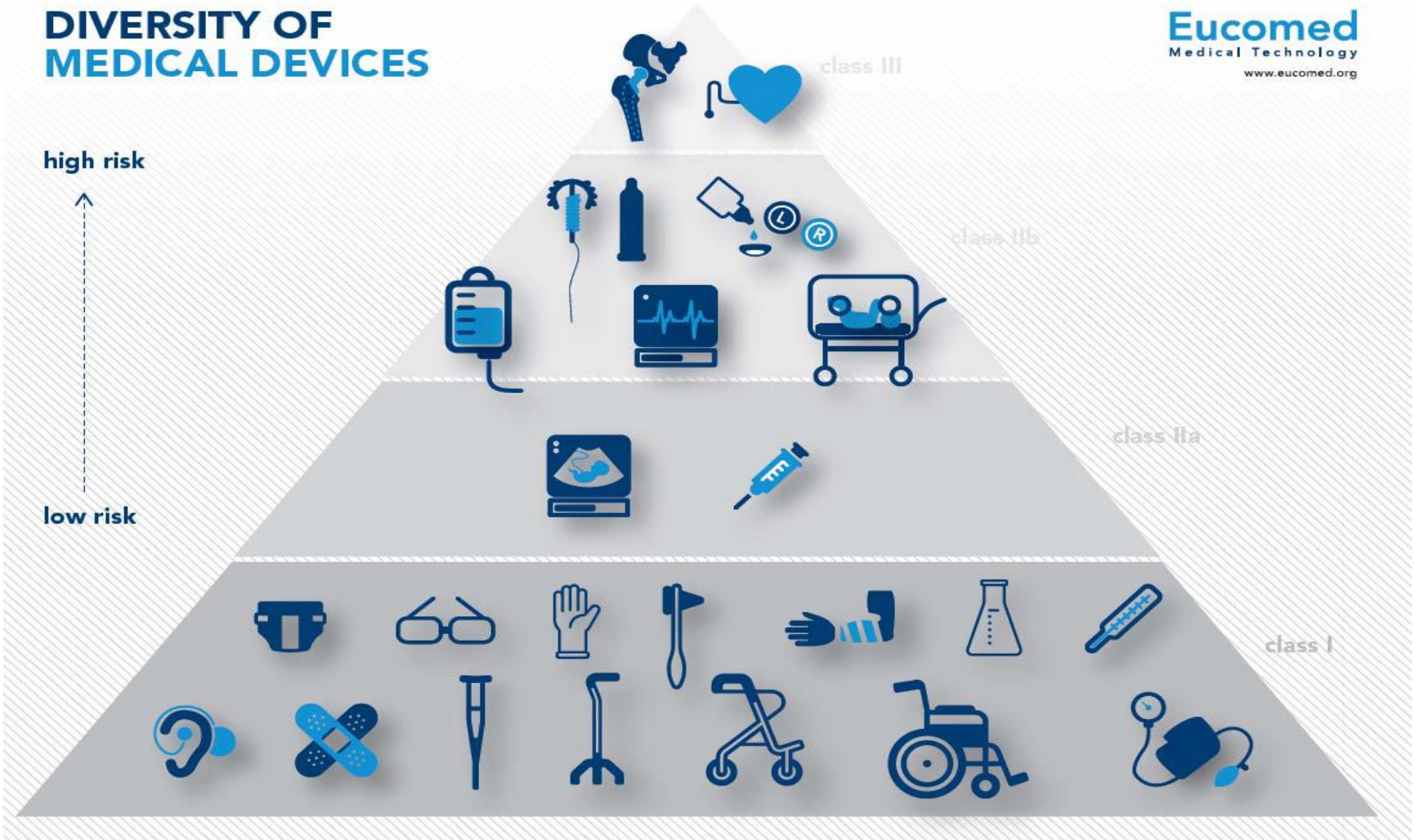
‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— 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.

DIVERSITY OF MEDICAL DEVICES

Eucomed
Medical Technology
www.eucomed.org



Medical device

custom-made device’

‘accessory for a medical device’

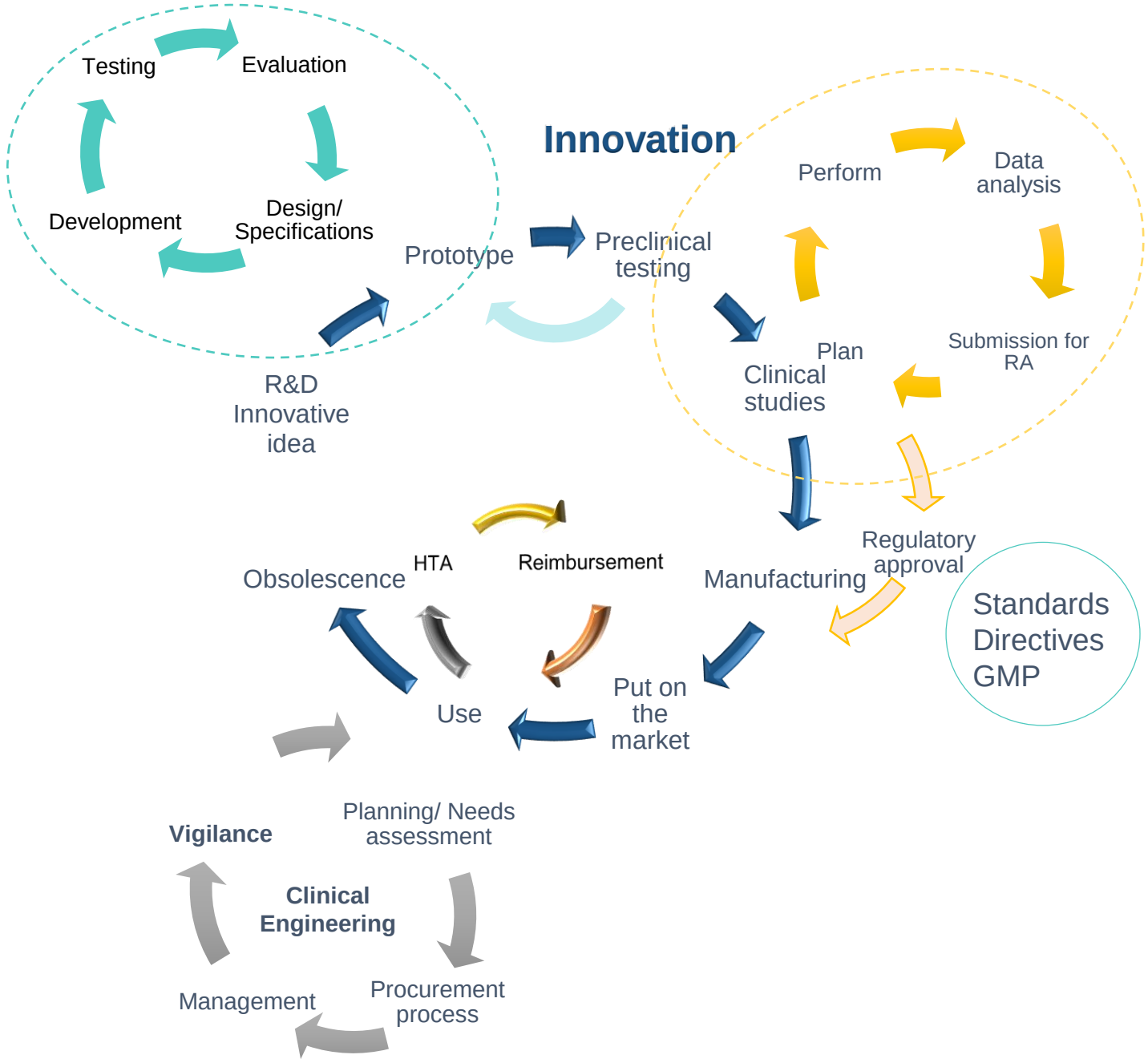
‘active device’

‘implantable device’

‘invasive device’

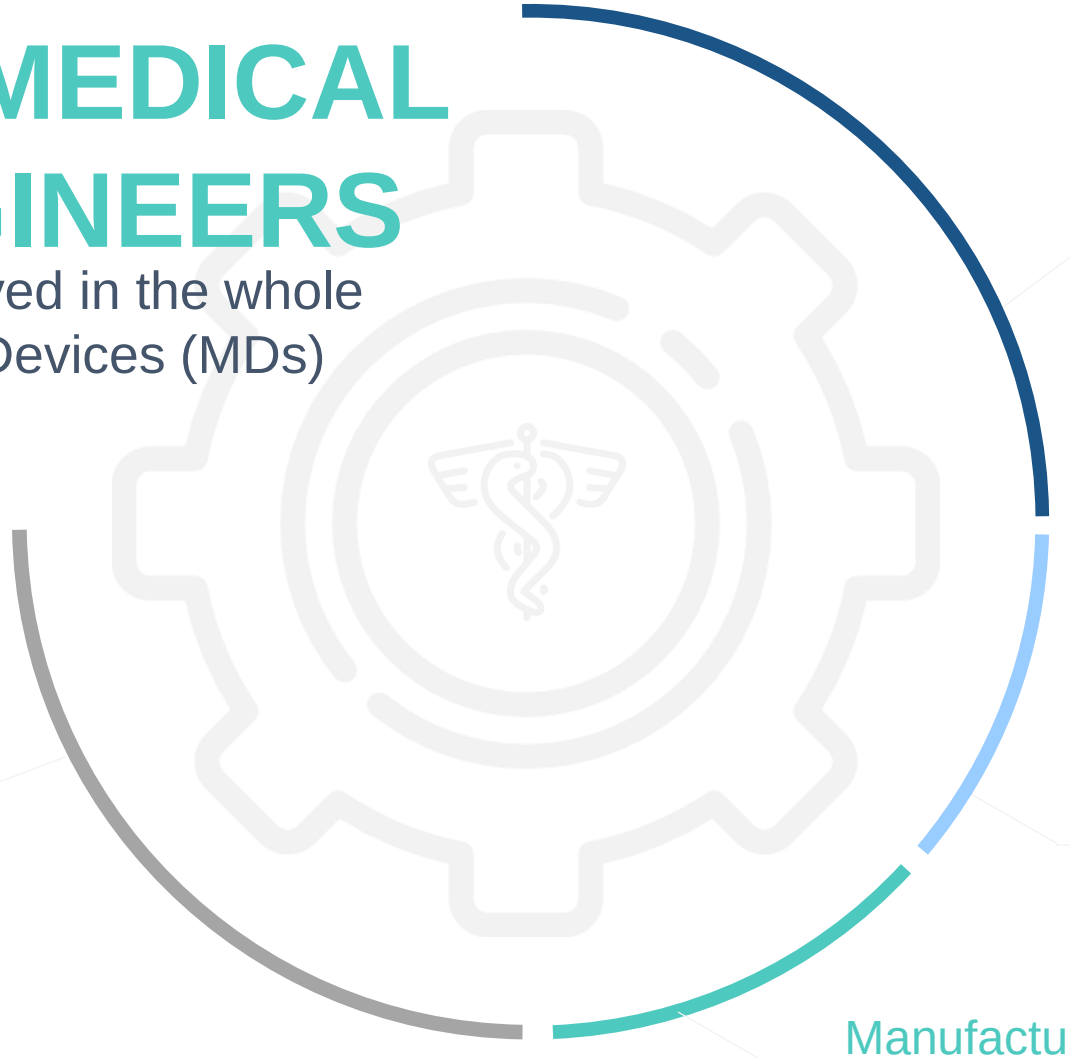
‘single-use device’

The Health Technology Life Cycle



BIOMEDICAL ENGINEERS

are involved in the whole Medical Devices (MDs) life cycle



Conceptual and R&D phases

Testing & Approval

Manufacturing

Clinical Engineering

Medical Technology Management

Regulations

All medical devices are produced and “placed on the market” according to international standards and have the necessary certification in compliance with the Medical Devices Directives and guidelines for the EU, and/or FDA approval for the US.

The New Approach

- One system for market authorisation
- Based on Directives and Harmonised standards
- CE mark
- Free movement in the EU

The Legal Framework in Europe for Medical Devices

DIRECTIVES

AIMD 90/385/EEC
MD 93/42/EEC
IVDs 98/79/EC

Replaced by the

REGULATIONS

2017/745 on MDs &

2017/746 ON IVDs

GUIDELINES

MEDDEV Series

CE MARK

Competent
Authorities
Notified Bodies

HARMONISED STANDARDS

EN SERIES

POST MARKET

Post Market surveillance

Vigilance

Classification

Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks.

22 Rules based approach described in Annex VIII of the regulation

- **DURATION OF USE**
- **INVASIVE AND ACTIVE DEVICES**
- **ACTIVE IMPLANTABLE DEVICES ARE CLASS III**

EUDAMED

European database on medical devices integrate different electronic systems to collate and process information regarding devices on the market

MDs Categories & Groups

- 12 to 30 Categories depending on the approach
- More than 10000 groups

Medical devices nomenclature

To facilitate the functioning of the European database on medical devices (‘Eudamed’) as referred to in Article 33, the Commission shall ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

GMDN
UMDNS
FDA
National nomenclature systems

Unique Device Identification system UDI

‘Unique Device Identifier’ (‘UDI’) is a series of numeric or alphanumeric characters that is created through in ternationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

The role of Competent Authorities and Notified Bodies

COMPETANT AUTHORITIES
Authorities responsible for the MD market in each country

NOTIFIED BODY
a conformity assessment body designated in accordance with the Regulations

conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

REGISTRATION

- Registration of manufacturers, authorised representatives and importers

- Registration of devices

The MDs Vigilance System

The principal purpose of the Medical Device Vigilance System is to improve the protection of health and safety of Patients, Users and others, by reducing the likelihood of reoccurrence of the INCIDENT elsewhere. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such incidents .

In other words reduce the Risks of adverse events

RISKS

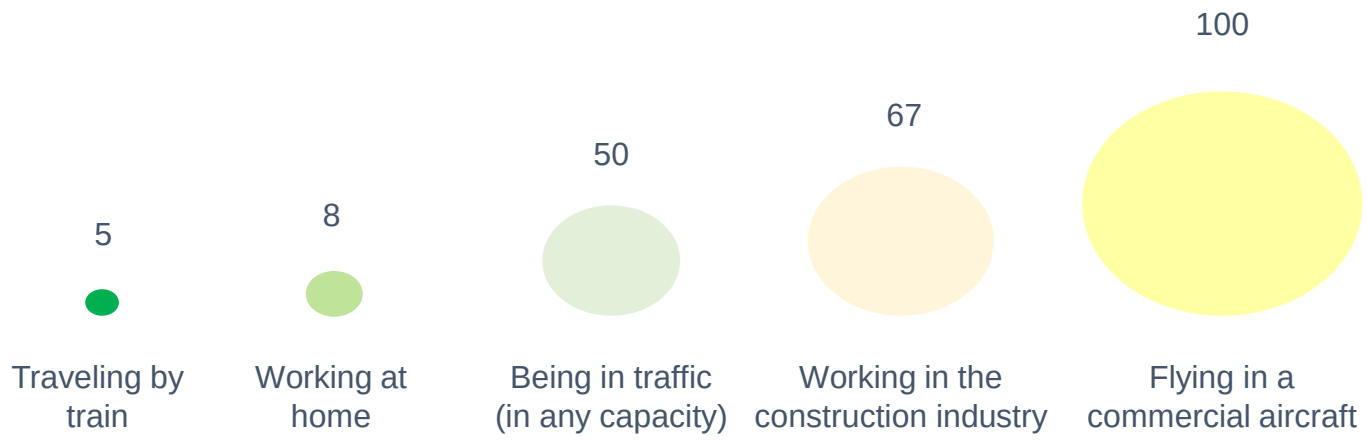
As **Risk** we mean the probability of occurrence of a hazardous situation, combined by the severity of the harm that it may produce.

In all human activities there is a Risk

RISKS

Some estimations of Risks, in terms of

Deaths per 100 millions hours of activity associated with:



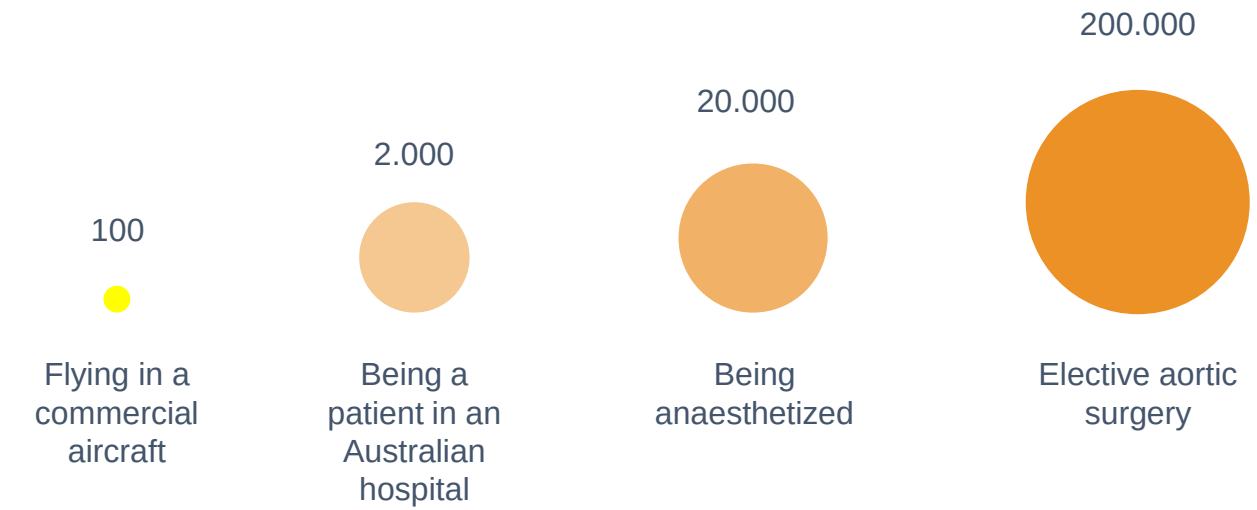
20.000

Parachute jumping

Ref. Bill Runciman
Australian Patient Safety Foundation
Australian Council for Safety and Quality in Healthcare

RISKS

Risks in terms of Deaths per 100 millions hours associated with:



Ref. Bill Runciman
Australian Patient Safety Foundation
Australian Council for Safety and Quality in Healthcare

Health Care Adverse Incident Types

Clinical process

- Medication

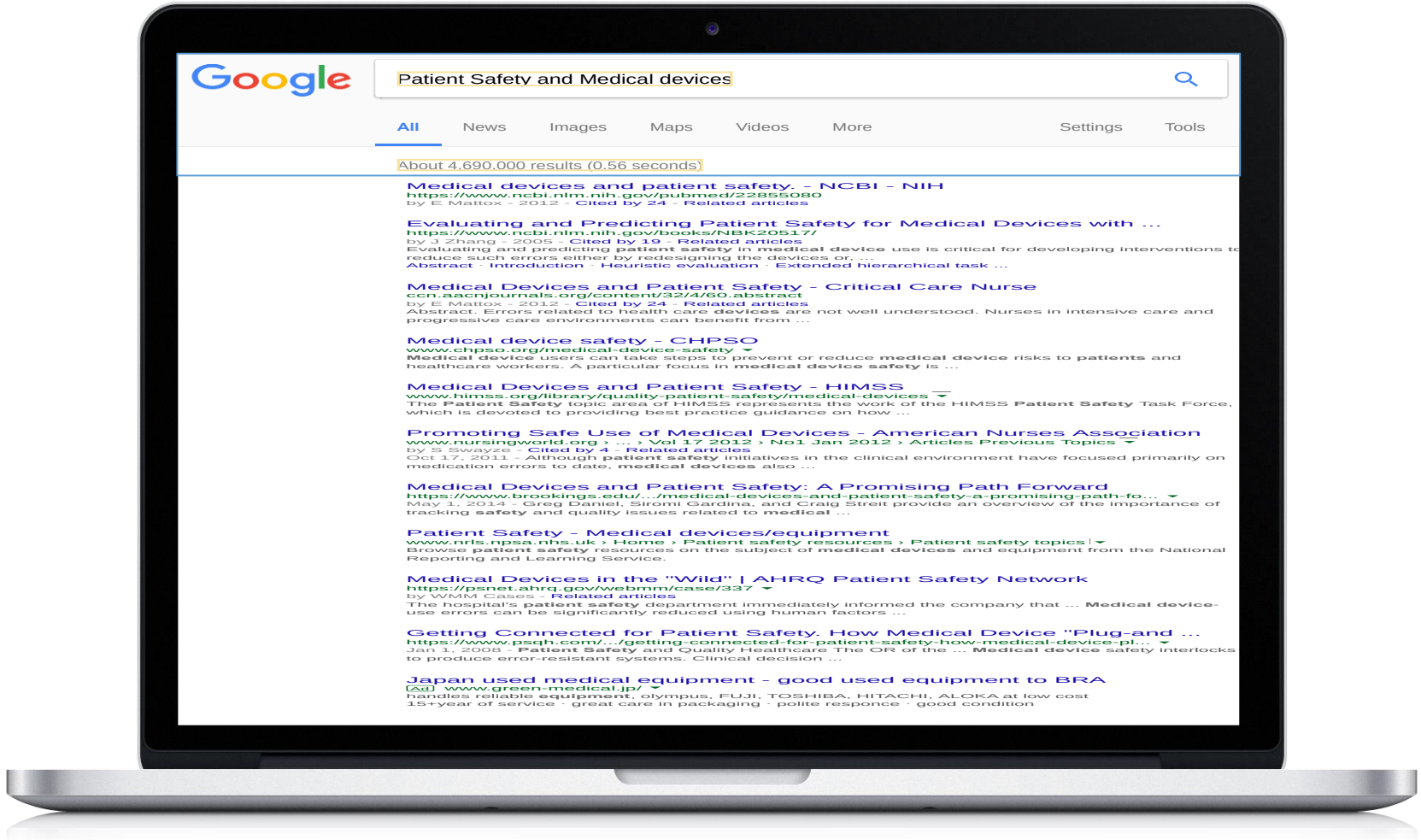
Specialties

- Anesthesia,
- Surgery,
- Intensive Care
- Laboratory testing

Services and infrastructure

- Medical devices

Other


Google
Patient Safety and Medical devices
All
News
Images
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Videos
More
Settings
Tools
About 4,690,000 results (0.56 seconds)
Medical devices and patient safety. - NCBI - NIH
https://www.ncbi.nlm.nih.gov/pubmed/22855080
by E Mattox - 2012 - Cited by 24 - Related articles
Evaluating and Predicting Patient Safety for Medical Devices with ...
https://www.ncbi.nlm.nih.gov/books/NBK20517/
by J Zhang - 2005 - Cited by 19 - Related articles
Evaluating and predicting patient safety in medical device use is critical for developing interventions to reduce such errors either by redesigning the devices or, ...
Abstract · Introduction · Heuristic evaluation · Extended hierarchical task ...
Medical Devices and Patient Safety - Critical Care Nurse
ccn.aacnjournals.org/content/32/4/60.abstract
by E Mattox - 2012 - Cited by 24 - Related articles
Abstract. Errors related to health care devices are not well understood. Nurses in intensive care and progressive care environments can benefit from ...
Medical device safety - CHPSO
www.chpso.org/medical-device-safety
Medical device users can take steps to prevent or reduce medical device risks to patients and healthcare workers. A particular focus in medical device safety is ...
Medical Devices and Patient Safety - HIMSS
www.himss.org/library/quality-patient-safety/medical-devices
The Patient Safety topic area of HIMSS represents the work of the HIMSS Patient Safety Task Force, which is devoted to providing best practice guidance on how ...
Promoting Safe Use of Medical Devices - American Nurses Association
www.nursingworld.org › ... › Vol 17 2012 › No1 Jan 2012 › Articles Previous Topics
by S Swayze - Cited by 4 - Related articles
Oct 17, 2011 - Although patient safety initiatives in the clinical environment have focused primarily on medication errors to date, medical devices also ...
Medical Devices and Patient Safety: A Promising Path Forward
https://www.brookings.edu/.../medical-devices-and-patient-safety-a-promising-path-fo...
May 1, 2014 - Greg Daniel, Siromi Gardina, and Craig Streit provide an overview of the importance of tracking safety and quality issues related to medical ...
Patient Safety - Medical devices/equipment
www.nrls.npsa.nhs.uk › Home › Patient safety resources › Patient safety topics
Browse patient safety resources on the subject of medical devices and equipment from the National Reporting and Learning Service.
Medical Devices in the "Wild" | AHRQ Patient Safety Network
https://psnet.ahrq.gov/webmm/case/337
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The hospital's patient safety department immediately informed the company that ... Medical device-use errors can be significantly reduced using human factors ...
Getting Connected for Patient Safety. How Medical Device "Plug-and ...
https://www.psqh.com/.../getting-connected-for-patient-safety-how-medical-device-pl...
Jan 1, 2008 - Patient Safety and Quality Healthcare The OR of the ... Medical device safety interlocks to produce error-resistant systems. Clinical decision ...
Japan used medical equipment - good used equipment to BRA
Ad www.green-medical.jp/
handles reliable equipment, olympus, FUJI, TOSHIBA, HITACHI, ALOKA at low cost
15+year of service · great care in packaging · polite responce · good condition

Back to the EU Medical Devices Vigilance System

The EU Medical Devices Vigilance System is described in details in the Medical Devices guidelines document
MEDDEV 2.12-1 rev 6

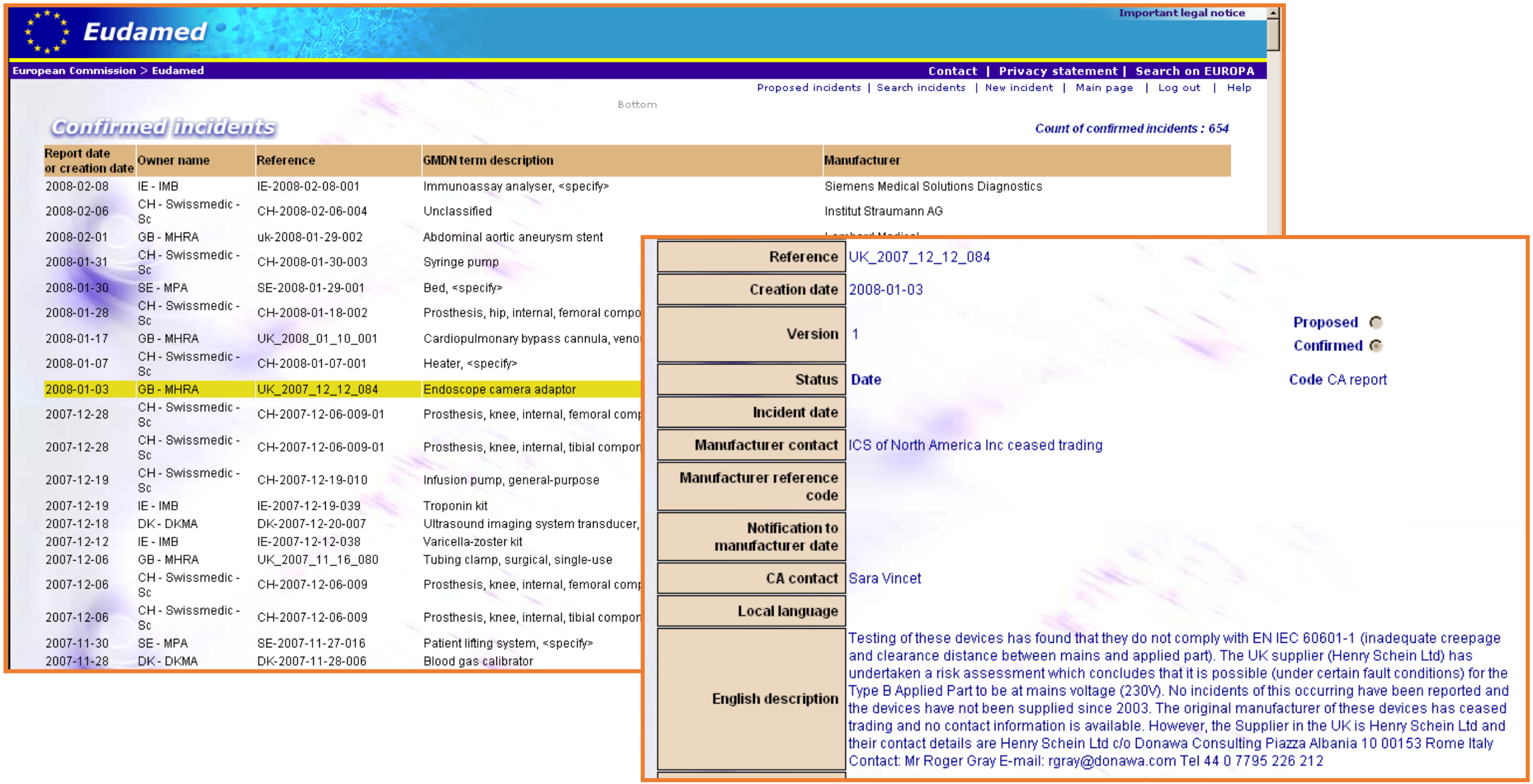
The EU, through the Medical Device Directives, imposed the use of a vigilance system in order to **prevent the reoccurrence** of adverse events that could lead to injuries or death of patients or personnel, due to equipment malfunction or improper use.

The EU Medical Device Vigilance approach

Early warning of adverse effects should be performed by users reporting to the national Competent Authorities (User Reporting System) or to manufacturers (Post Market Surveillance)

The Medical Devices Vigilance System is essential for the creation of a safer environment in healthcare and a condition for the prevention of adverse events

EUDAMED



Eudamed

Important legal notice

European Commission > Eudamed

Contact | Privacy statement | Search on EUROPA

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Confirmed incidents

Count of confirmed incidents : 654

Report date or creation date	Owner name	Reference	GMDN term description	Manufacturer
2008-02-08	IE - IMB	IE-2008-02-08-001	Immunoassay analyser, <specify>	Siemens Medical Solutions Diagnostics
2008-02-06	CH - Swissmedic - Sc	CH-2008-02-06-004	Unclassified	Institut Straumann AG
2008-02-01	GB - MHRA	uk-2008-01-29-002	Abdominal aortic aneurysm stent	
2008-01-31	CH - Swissmedic - Sc	CH-2008-01-30-003	Syringe pump	
2008-01-30	SE - MPA	SE-2008-01-29-001	Bed, <specify>	
2008-01-28	CH - Swissmedic - Sc	CH-2008-01-18-002	Prosthesis, hip, internal, femoral compo	
2008-01-17	GB - MHRA	UK_2008_01_10_001	Cardiopulmonary bypass cannula, veno	
2008-01-07	CH - Swissmedic - Sc	CH-2008-01-07-001	Heater, <specify>	
2008-01-03	GB - MHRA	UK_2007_12_12_084	Endoscope camera adaptor	
2007-12-28	CH - Swissmedic - Sc	CH-2007-12-06-009-01	Prosthesis, knee, internal, femoral comp	
2007-12-28	CH - Swissmedic - Sc	CH-2007-12-06-009-01	Prosthesis, knee, internal, tibial compon	
2007-12-19	CH - Swissmedic - Sc	CH-2007-12-19-010	Infusion pump, general-purpose	
2007-12-19	IE - IMB	IE-2007-12-19-039	Troponin kit	
2007-12-18	DK - DKMA	DK-2007-12-20-007	Ultrasound imaging system transducer,	
2007-12-12	IE - IMB	IE-2007-12-12-038	Varicella-zoster kit	
2007-12-06	GB - MHRA	UK_2007_11_16_080	Tubing clamp, surgical, single-use	
2007-12-06	CH - Swissmedic - Sc	CH-2007-12-06-009	Prosthesis, knee, internal, femoral comp	
2007-12-06	CH - Swissmedic - Sc	CH-2007-12-06-009	Prosthesis, knee, internal, tibial compon	
2007-11-30	SE - MPA	SE-2007-11-27-016	Patient lifting system, <specify>	
2007-11-28	DK - DKMA	DK-2007-11-28-006	Blood gas calibrator	

Reference	UK_2007_12_12_084
Creation date	2008-01-03
Version	1
Status	**Date**
Incident date	
Manufacturer contact	ICS of North America Inc ceased trading
Manufacturer reference code	
Notification to manufacturer date	
CA contact	Sara Vincet
Local language	
English description	Testing of these devices has found that they do not comply with EN IEC 60601-1 (inadequate creepage and clearance distance between mains and applied part). The UK supplier (Henry Schein Ltd) has undertaken a risk assessment which concludes that it is possible (under certain fault conditions) for the Type B Applied Part to be at mains voltage (230V). No incidents of this occurring have been reported and the devices have not been supplied since 2003. The original manufacturer of these devices has ceased trading and no contact information is available. However, the Supplier in the UK is Henry Schein Ltd and their contact details are Henry Schein Ltd c/o Donawa Consulting Piazza Albania 10 00153 Rome Italy Contact: Mr Roger Gray E-mail: rgray@donawa.com Tel 44 0 7795 226 212

Proposed ○
Confirmed ◉

Code CA report

Vigilance

Responsible Organization:

- FDA - Center for Devices and Radiological Health

Database:

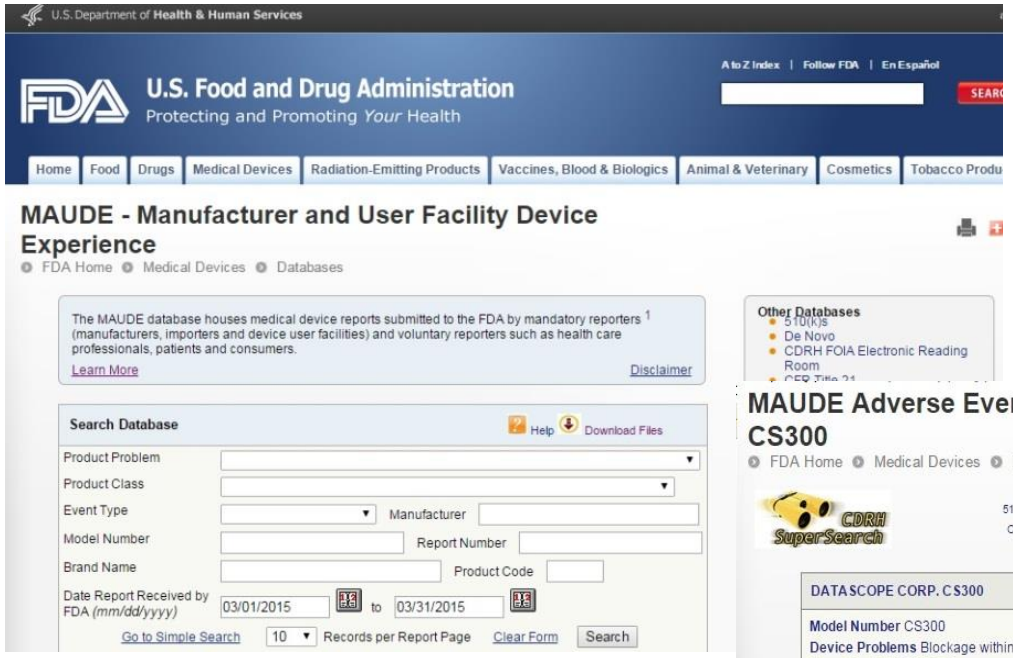
- Manufacturer and User Facility Device Experience

5.625.939

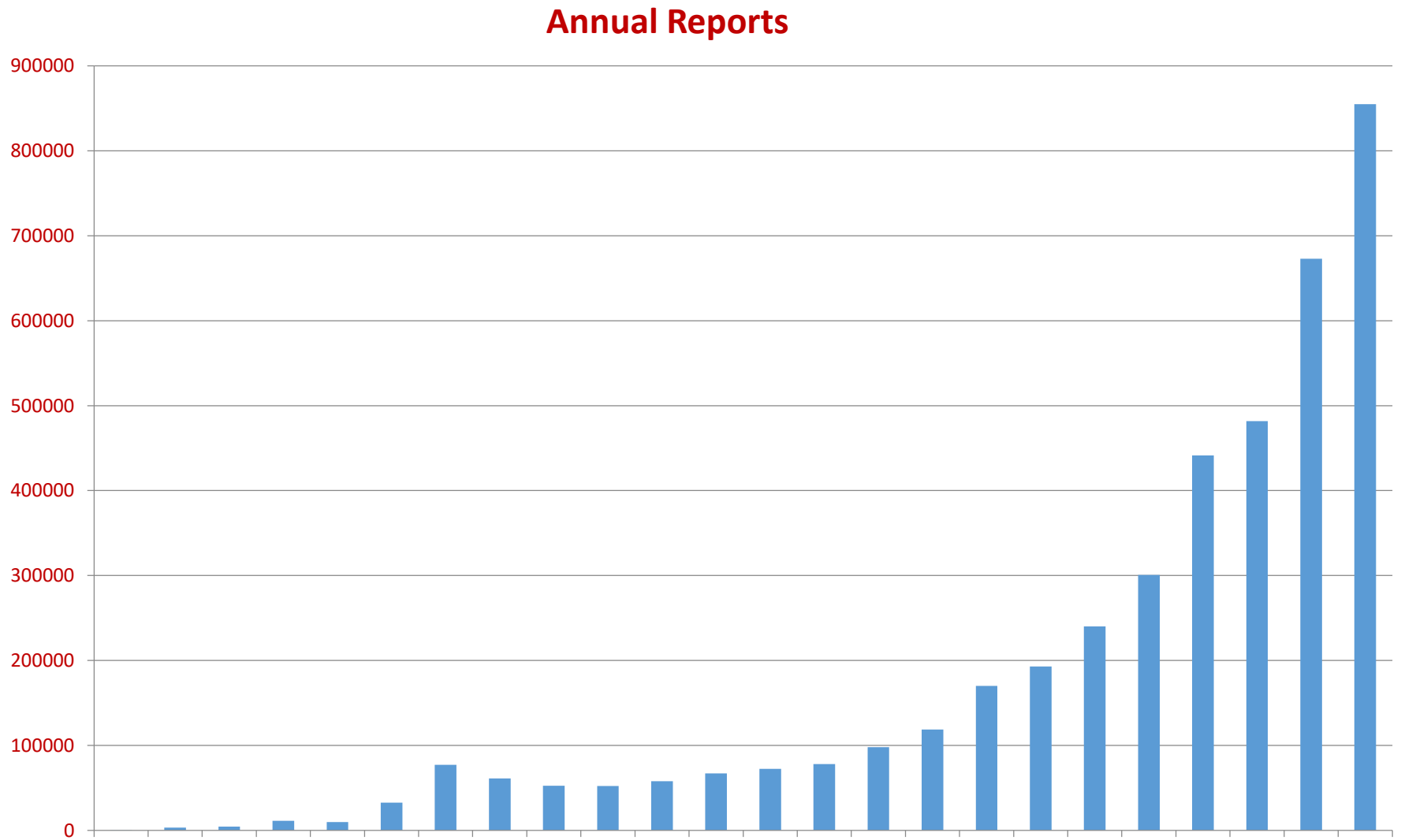
Reports submitted

(September 2016)

MAUDE Report



Reports to MAUDE annually



Vulnerability of software-based MD

- The more complex software gets, the more rarely is 'bug-free'

‘It is estimated that for every 1,000 lines of code you will get a bug, and medical devices have hundreds of thousands, sometimes millions, of lines of code’ !

Vulnerability of software-based MD

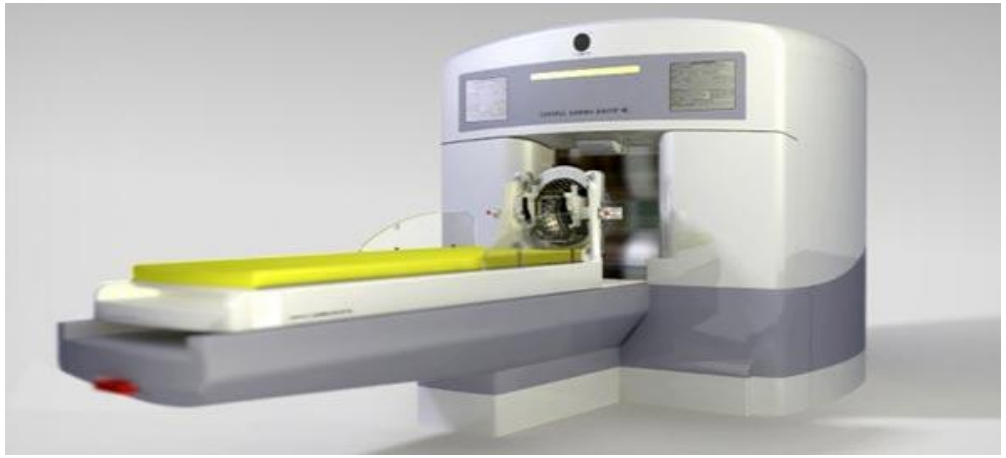
Two concerns: software bugs and hacking

- According to The Economist, software errors in drug pumps were involved in 20,000 serious injuries and 700 deaths between 2005 and 2009
- MDs that are networked can be open to hacking i.e. Implantable defibrillator is susceptible to being reprogrammed to withhold treatment or to deliver unnecessary shocks

Adverse events due to Software

Therac-25 Medical Accelerator

Among the Top 10 “costliest” Software Bugs

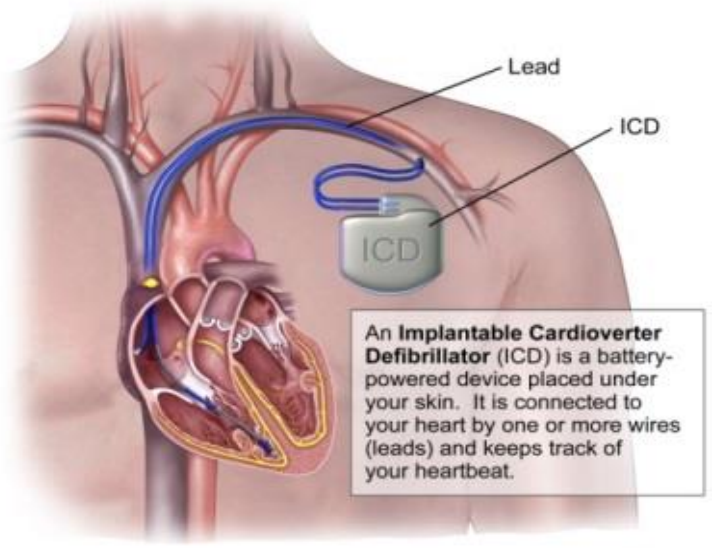


The machine massively overdosed patients between June 1985 and January 1987. The power of the electron beam reached such a high power that it lead to the death of 5 patients and injured the rest severely

Adverse events due to Software

From 1997 to 2003, an estimated 450,000 ICDs were implanted world-wide and the majority of the procedures took place in the US

At least 212 deaths from device failures in 5 different brands of ICD occurred during this period, according to a study reported to the FDA



THANK YOU

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