Medical Testing of active medical products

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TÜV SÜD at a glance

150+
YEARS OF QUALITY, SAFETY & SUSTAINABILITY

1,000+
LOCATIONS WORLDWIDE

€2.4
BILLION IN ANNUAL REVENUE

24,000+
EMPLOYEES*

42%
OF REVENUE OUTSIDE GERMANY^

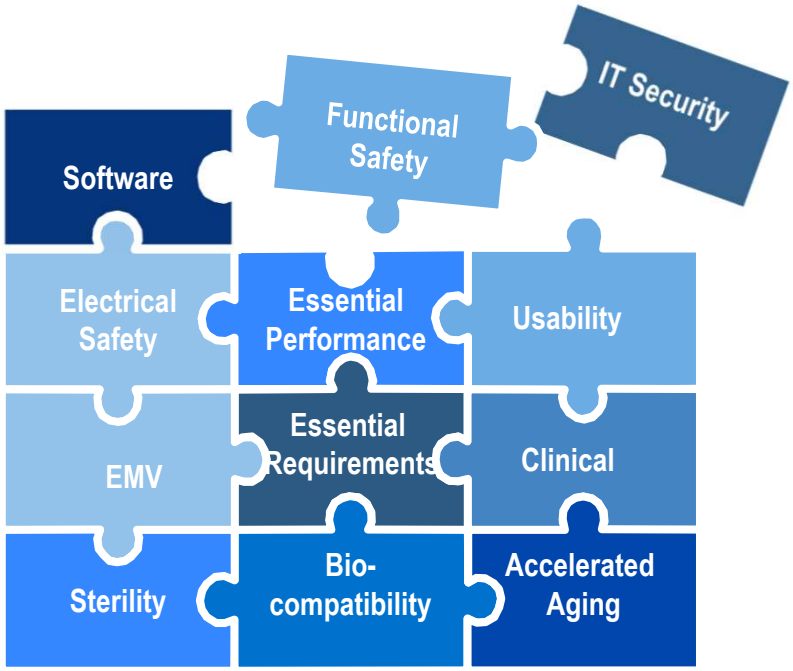
574,000
CERTIFICATES

100%
INDEPENDENT & IMPARTIAL

1-STOP SOLUTIONS PROVIDER

*As of 2017-12-31
^Based on clients' locations
Note: Figures have been rounded off.

Overview



Medical Testing

Example

Management Systems

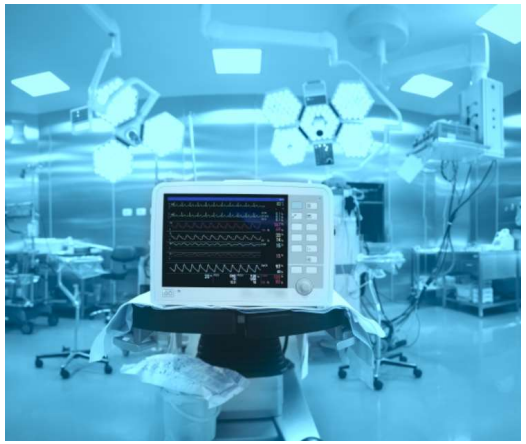
ISO 9001 Quality Management
ISO 13485 Medical Devices – Quality Management Systems
ISO 14001 environmental management
ISO 50001 energy management

Functional safety risk assessment, software

EN/IEC 62304 medical device software
ISO 14971 Risk Management Process

RoHS/REACH/WEE

2002/95/EG ROHS (Restriction of Hazardous Substances)
2002/96/EG (Waste Electrical & Electronic Equipment
EG 1907/2006 (Registration, Evaluation, Authorization of Chemicals)



Conformity assessment

MDD and MDR (CE0123)

Testing standards

Medical standards: EN/IEC 60601-1, ANSI AMI 60601-1, NRTL, CB,
Power supplies: IEC 60950-1, UL/CSA 60950-1
Laser: IEC 60825-1
Licht: IEC 62471 photobiological safety
Cybersecurity: IEC/TS 62443-1-1, IEC 80001-2-8
EMC: IEC 60601-1-2 / 4th Edition
Ultrasound: IEC 60601-2-37

Environmental & Transport

ASTM & ISTA
EN 60529
ISO 9227 NSS
ISO 6270-2
……

EMC- / Radio Directive

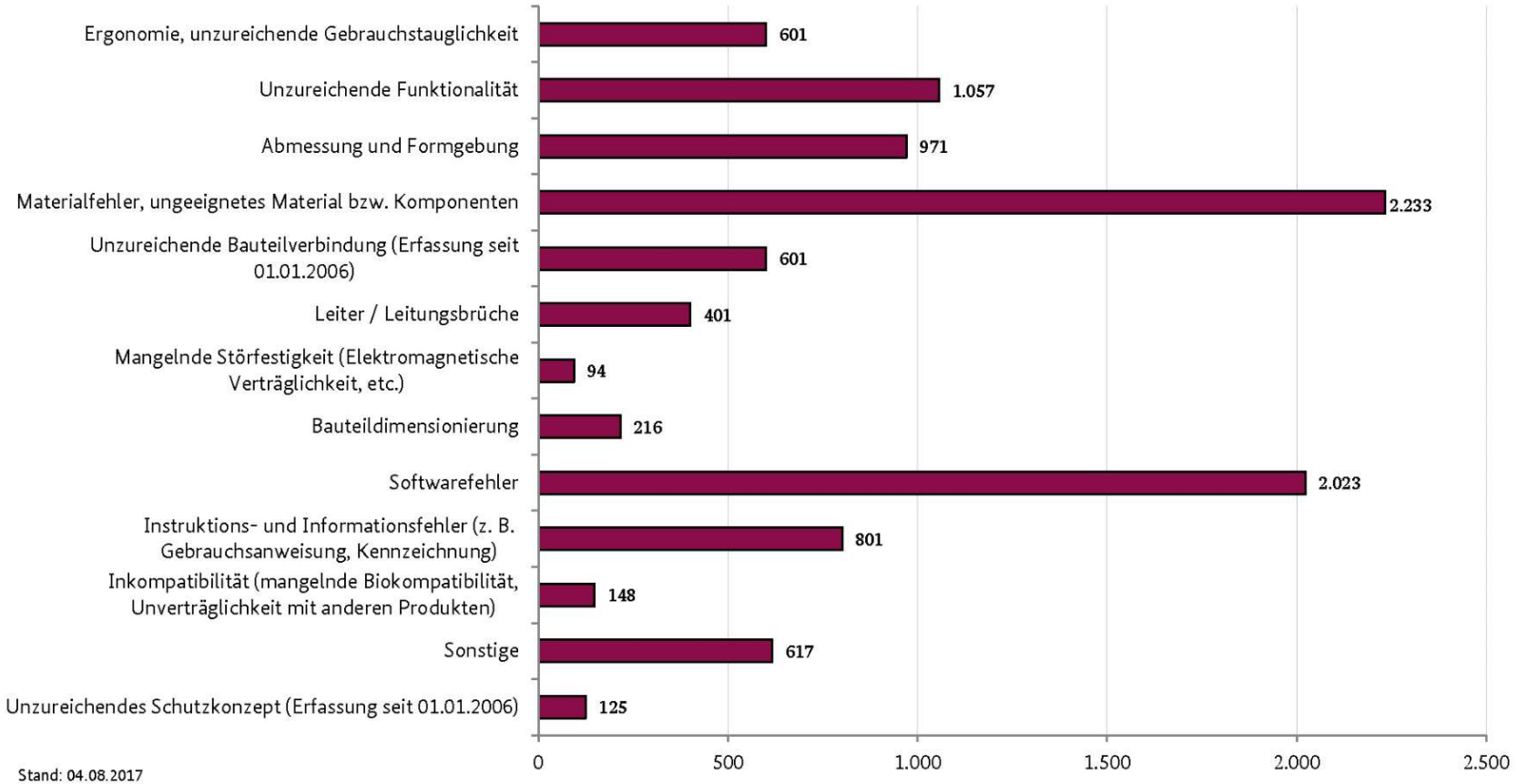
EMC directive: 2004/108/EG
RED directive: 2014/53/EU

BfArM / product issues

Bundesinstitut für Arzneimittel und Medizinprodukte

Statistische Auswertung der im Zeitraum 01.01.2005 bis 31.12.2016 abschließend bewerteten Risikomeldungen

Fehlerursache: Design- / Konstruktionsfehler



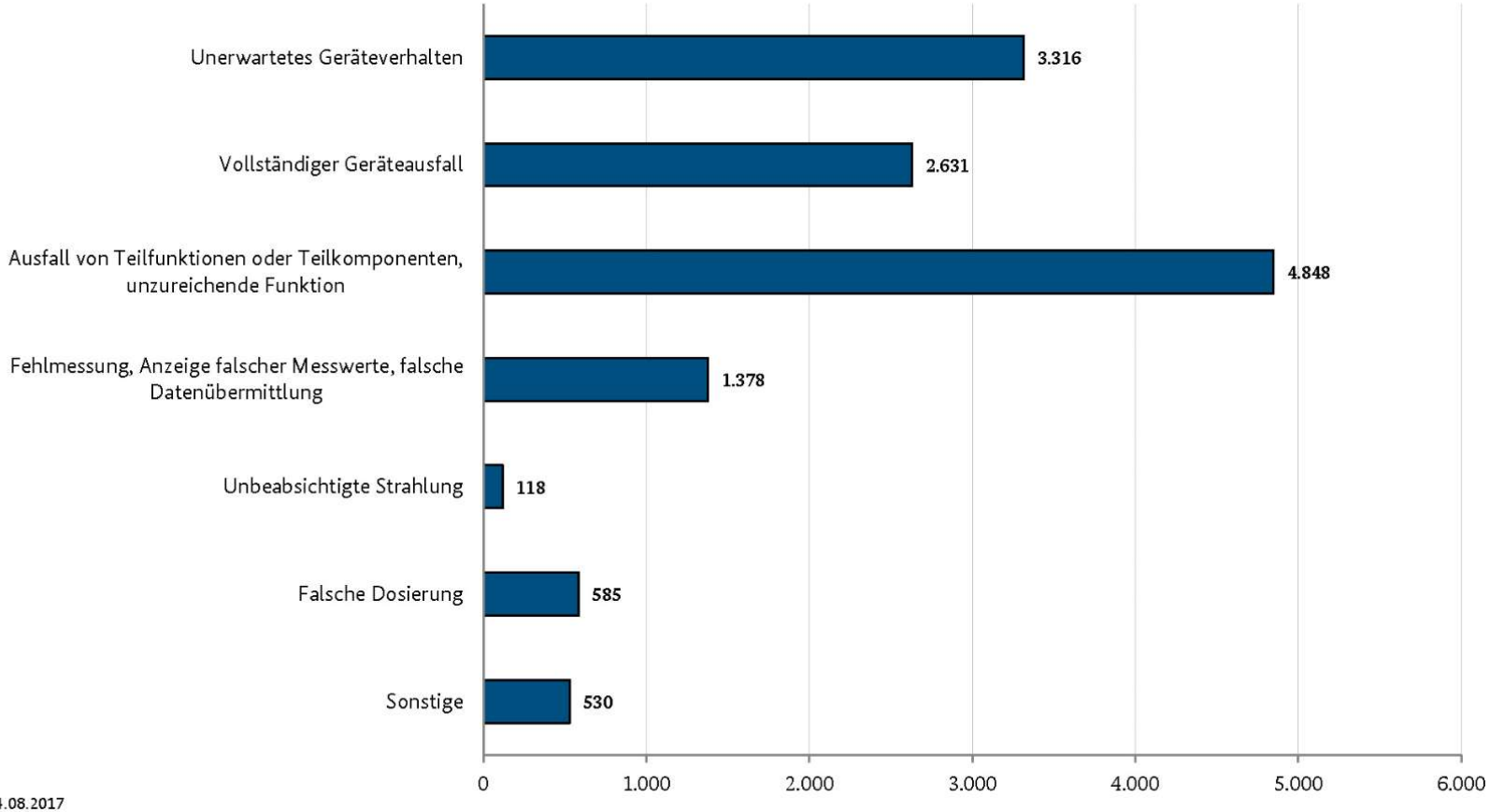
Stand: 04.08.2017
Summe: 9.888

BfArM / product issues

Bundesinstitut für Arzneimittel und Medizinprodukte

Statistische Auswertung der im Zeitraum 01.01.2005 bis 31.12.2016 abschließend bewerteten Risikomeldungen

Fehlerart: Funktionsausfälle und Fehlfunktionen



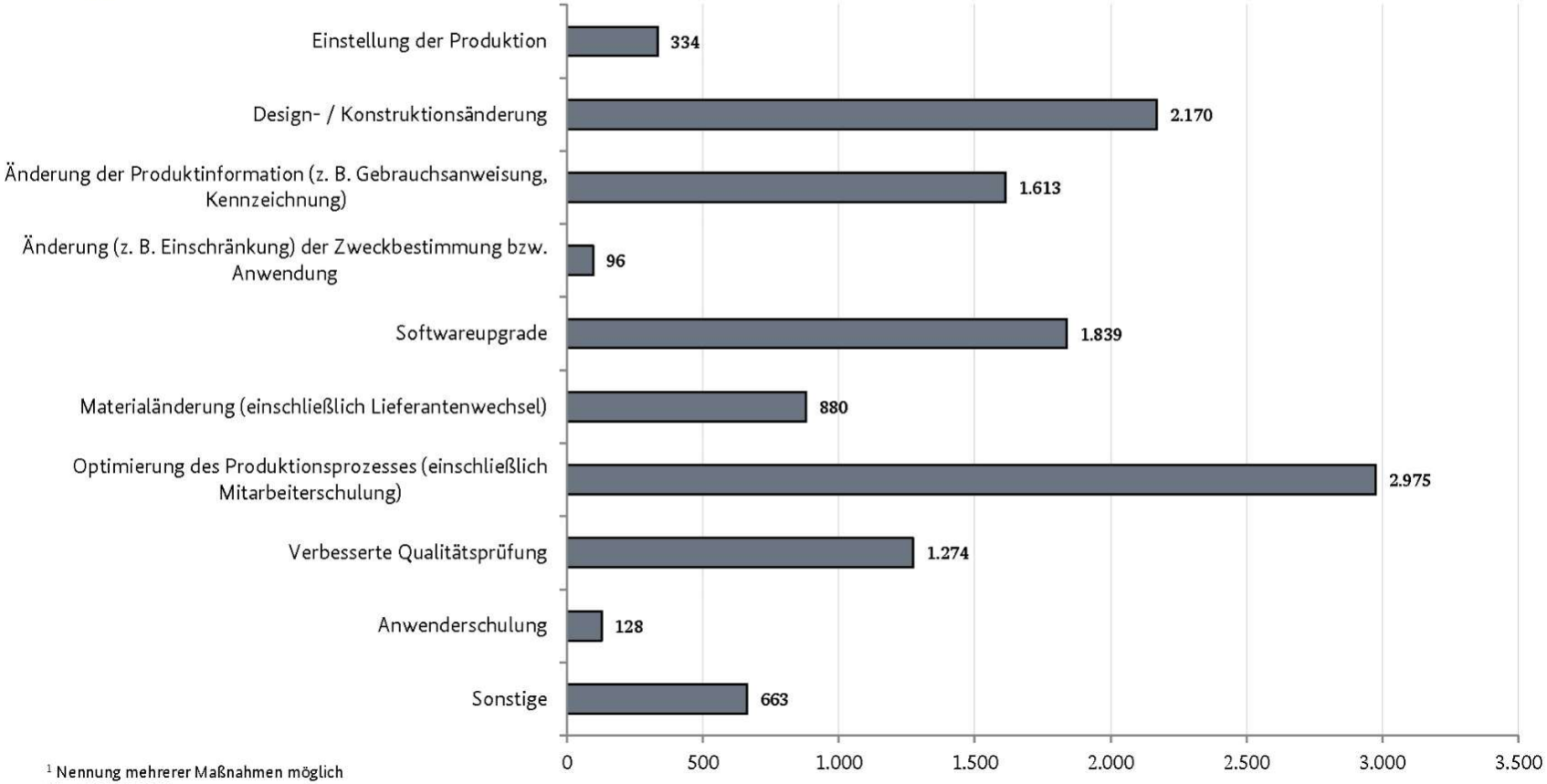
Stand: 04.08.2017
Anzahl: 13.406

BfArM / corrective actions

Bundesinstitut für Arzneimittel und Medizinprodukte

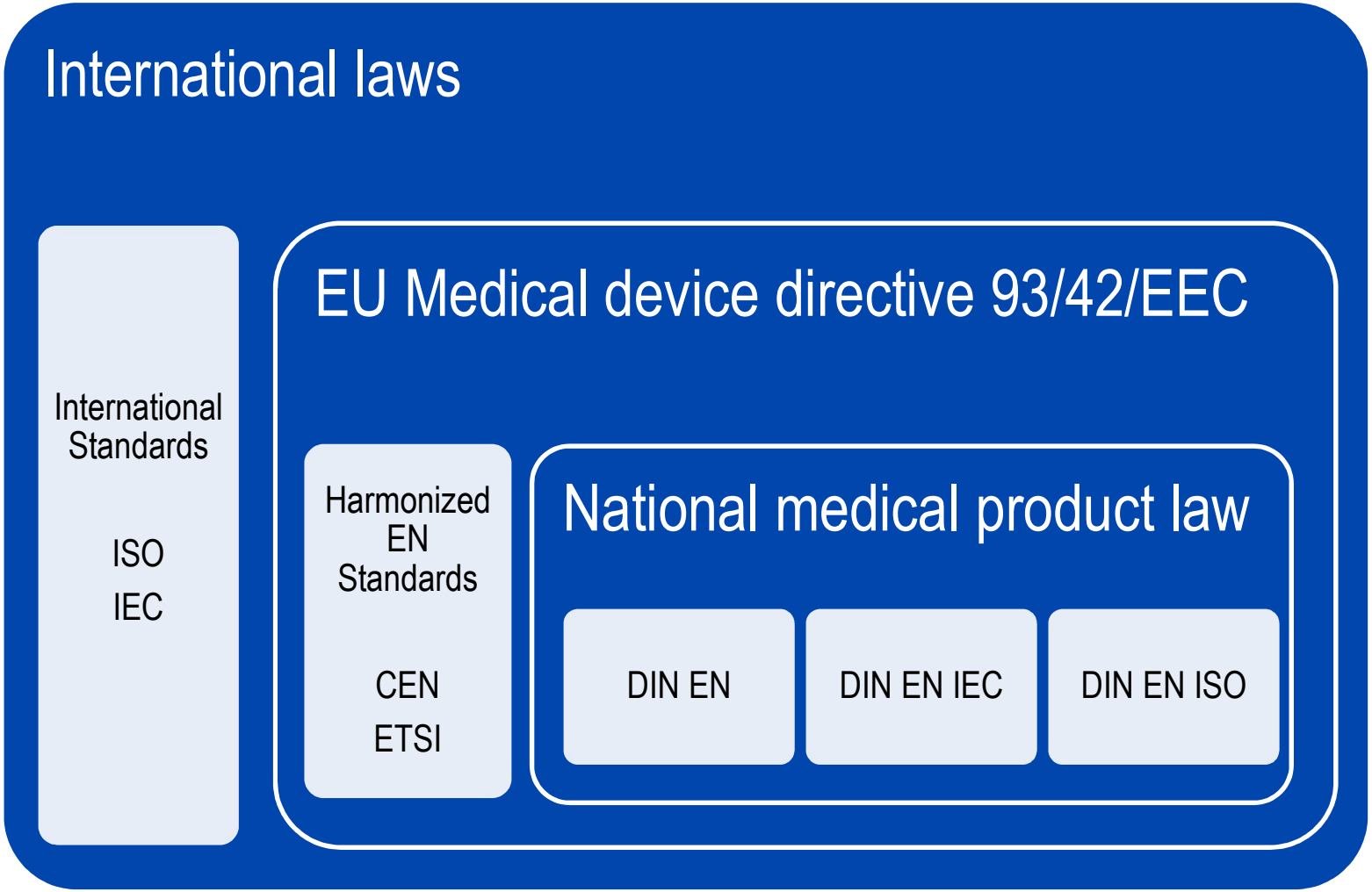
Statistische Auswertung der im Zeitraum 01.01.2005 bis 31.12.2016 abschließend bewerteten Risikomeldungen

Maßnahmen zur Beseitigung der Ursachen
(für zukünftige Produkte)[1]



[1] Nennung mehrerer Maßnahmen möglich
Stand: 04.08.2017
Anzahl ausgewerteter Risikomeldungen: 61.224, 49.252 Risikomeldungen führten zu keinen Maßnahmen

Regulations and Standards



MDD Directive 93/42/EEC

- The conformity of a product is assessed before it is placed on the market.
- It needs to demonstrate that all legislative requirements are met.
- It includes testing, inspection and certification.
- To demonstrate that a product being placed on the market complies with all legislative requirements.

CE

Essential Requirements Annex I

Medical Device Directive / MDD

- demonstrate conformity with the essential requirements
- enable conformity to be verified, it is desirable to have
- harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices

CE

Essential Requirements Annex I

Medical Device Directive / MDD

The devices must be designed and manufactured in such a way that, when used under the conditions:

- for the purposes of intended use,
- Taking account of generally acknowledged state of the art
- Achieve performance under clinical purpose
- Taking account of Transport
- Considering side effect and acceptable risk

Declaration of Conformity (CE)

- the product
- the legislation according to which it is issued
- the manufacturer or the authorized representative
- the notified body if applicable
- a reference to harmonized standards or other normative documents, where appropriate.

CE

Harmonized Standards / Official Journal List (OJ)

Harmonized Standards / Official Journal List (OJ) is published by the European Union

- Considering European standards
- Developed by a recognized European Organization e.g. CEN, CENELEC, ETSI
- Manufacturers can use harmonized standards to demonstrate that products, services, or processes comply with relevant EU legislation
- Use of Standards is voluntary
- Manufacturer are free to choose another technical solution to demonstrate compliance with the mandatory legal requirements

Using of Harmonized Standards as listed in the OJ-list = Presumption (!) of conformity of the Essential Requirements as listed in Annex I of the MDD.

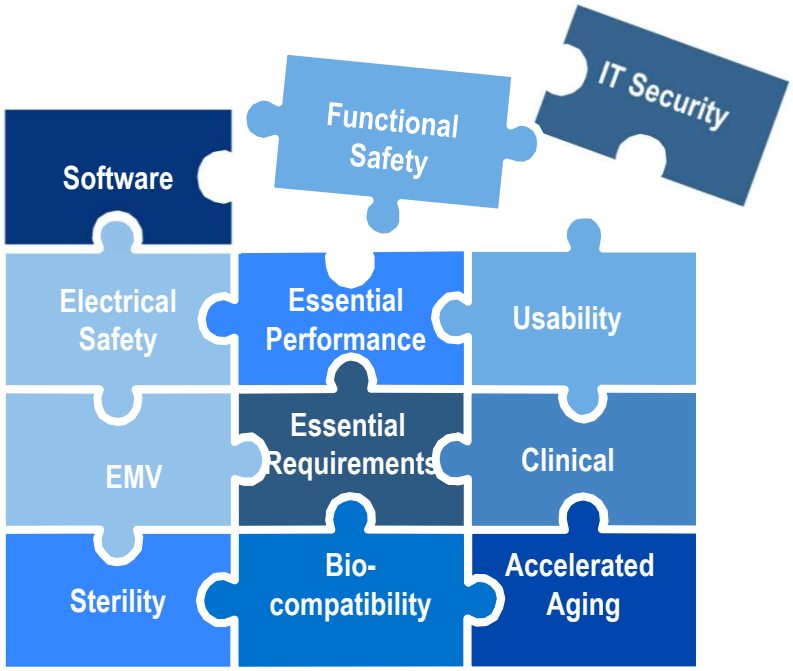
Harmonized Standards / Official Journal List (OJ)

Medical Device Directive / MDD

(1)	(2)	(3)	(4)	(5)
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-1:2006 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005	27.11.2008	EN 60601-1:1990 + A13:1996 + A1:1993 + A2:1995 EN 60601-1-1:2001 EN 60601-1-4:1996 + A1:1999 Note 2.1	1.6.2012
	EN 60601-1:2006/AC:2010	18.1.2011		
	EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012	16.5.2014	Note 3	31.12.2017
Addendum to Note 1 and Note 3 concerning dates of cessation of presumption of conformity when applying EN 60601-1:2006. The date of cessation of presumption of conformity when applying EN 60601-1:2006 is 31.12.2017. However the Annex ZZ to EN 60601-1:2006 ceases to specify the presumption of conformity with the Essential Requirements of Directive 93/42/EEC on 31.12.2015. As from 1.1.2016, only the clauses and sub-clauses of EN 60601-1:2006 corresponding to the clauses and sub-clauses referred to in Annex ZZ to EN 60601-1:2006/A1:2013 provide presumption of conformity with the Essential Requirements of Directive 93/42/EEC, to the extent indicated in the Annex ZZ to EN 60601-1:2006/A1:2013.				
Cenelec	EN 60601-1-1:2001 Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-1:2000	14.11.2001	EN 60601-1-1:1993 + A1:1996 Note 2.1	1.11.2003
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-1-2:2015 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests IEC 60601-1-2:2014	13.5.2016	EN 60601-1-2:2007 Note 2.1	31.12.2018

Problem:
Today: Around **250 newer standards are missing in the OJ-list** !

Overview



Regulations & Standards

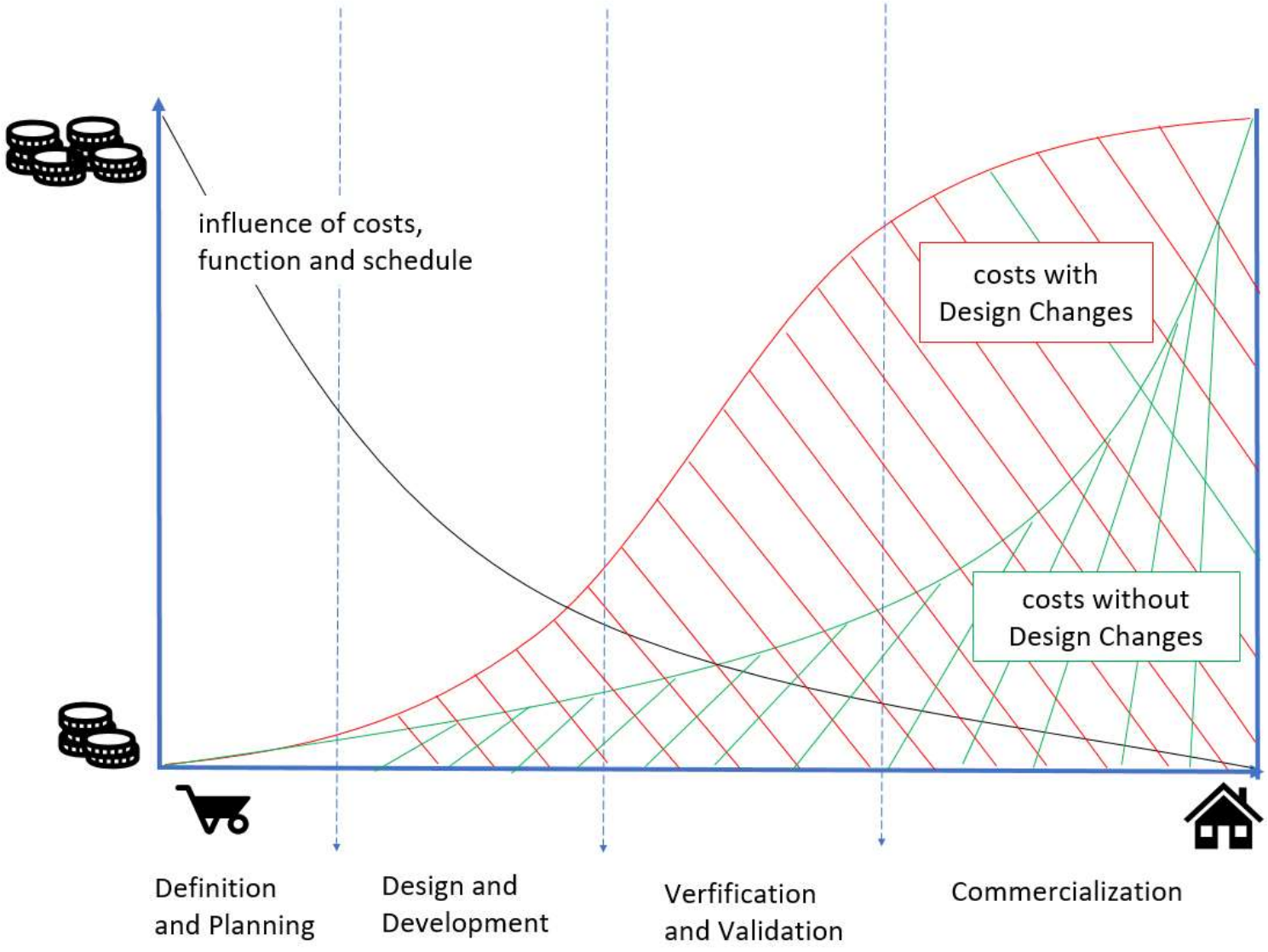
Design control requirements

Testing during Product Development

Testing Procedures & Certification

Summary

Costs of Design Changes



Design Control requirements for medical devices

Medical Testing

Design Control Element Applied	(21 – CFR Part 820)	§ ISO 13485	‡ ISO 14971
Design & Development Planning	820.30(b) Design & Development Planning	§ 7.3.1	
Design Input	820.30(c) Design Input	§ 7.3.2	
Product Risk Management		§ 7.1	‡
Design Output	820.30(d) Design Output	§ 7.3.3	
Design Review	820.30(e) Design Review	§ 7.3.4	
Design Verification	820.30(f) Design Verification `	§ 7.3.5	
Design Validation	820.30(g) Design Validation	§ 7.3.6	
Design Transfer	820.30(h) Design Transfer	§ 7.3.1	
Design Change	820.30(i) Design Change	§ 7.3.7	
Design History File	820.30(j) Design History File	§ 7.3.1	

Design Input – Design and development inputs

Design Control

- 13485:2016 – Chapter 7.3.2

  Inputs relating to product requirements shall be determined and records maintained.

  These inputs shall include:

  a) functional, performance, usability and safety requirements, according to the intended use;
  b) applicable regulatory requirements and standards;
  c) applicable output(s) of risk management;
  d) as appropriate, information derived from previous similar designs;
  e) other requirements essential for design and development of the product and processes.

- FDA 21 CFR 820.30(c) Design Input
  - Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intend use of the device, including the needs of the user and patient.
  - The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements.
  - The design input requirements shall be documented and shall be reviewed and approved by designated individual(s).
  - The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

Design Output – Design and development outputs

Design Control

- 13485:2016 – Chapter 7.3.4

  Design and development outputs shall:

  a) meet the input requirements for design and development;

  b) provide appropriate information for purchasing, production and service provision;

  c) contain or reference product acceptance criteria;

  d) specify the characteristics of the product that are essential for its safe and proper use.

- FDA 21 CFR 820.30(d) Design Output
  - Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.
  - Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified.
  - Design output shall be documented, reviewed, and approved before release.
  - The approval, including the date and signature of the individual(s) approving the output, shall be documented.

Design Verification – Design and development verification

Design Control

- 13485:2016 – Chapter 7.3.6

  Design and development outputs shall:

  – ensure that the design and development outputs have met the design and development input requirements
  – document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.
  – verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.
  – Records of the results and conclusions of the verification and necessary actions shall be maintained.

- FDA 21 CFR 820.30(f) Design verification

  – Each manufacturer shall establish and maintain procedures for verifying the device design.
  – Design verification shall confirm that the design output meets the design input requirements.
  – The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

Design Validation – Design and development validation

Design Control

- 13485:2016 – Chapter 7.3.7

  Design and development validation:

  - ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.
  - document validation plans
  - conducted on representative product e.g. representative product includes initial production units, batches or their equivalents.
  - perform clinical evaluations or performance evaluations of the medical device.
  - include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.
  - be completed prior to release for use of the product to the customer.

- FDA 21 CFR 820.30(g) Design validation

  - Each manufacturer shall establish and maintain procedures for validating the device design.
  - Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.
  - Design validation shall include software validation and risk analysis, where appropriate.
  - The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

Design Change – Control of design and development changes

Design Control

- 13485:2016 – Chapter 7.3.9

  control design and development changes:

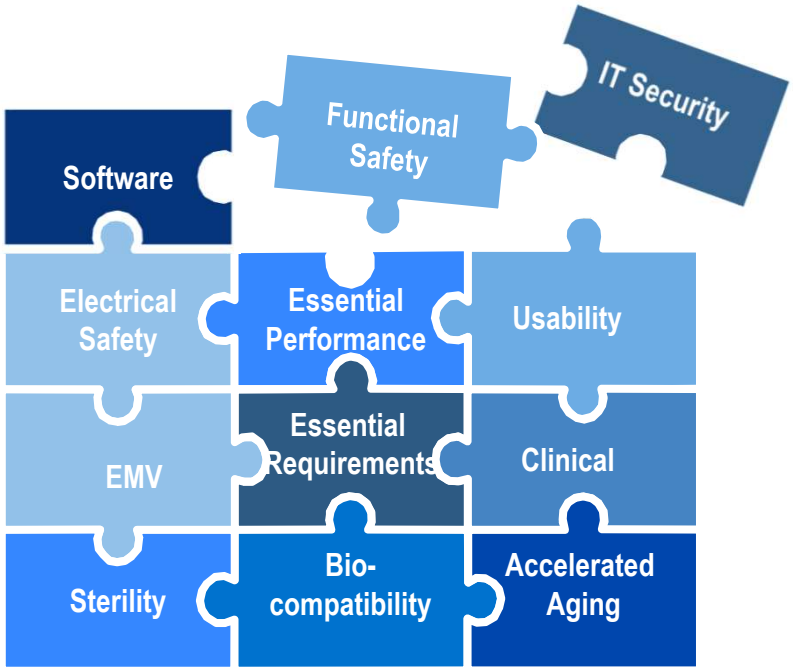
  – determine the significance of the change to function, performance, usability, safety applicable regulatory requirements for the medical device and its intended use.

  – Change shall be reviewed, verified, validated

- FDA 21 CFR 820.30(i) Design validation

  – Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

Overview



- Regulations & Standards
- Design Control requirements
- Testing during Product Development
- Testing Procedures & Certification
- Summary

Medical Testing

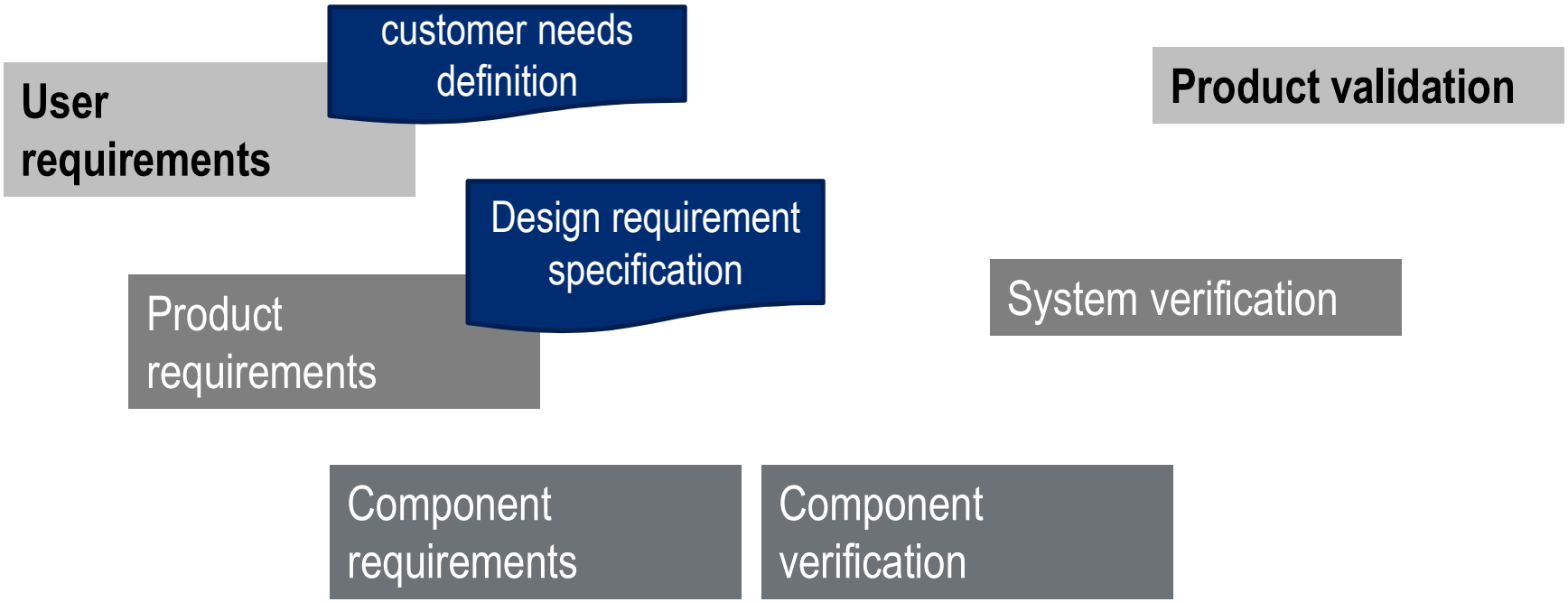
testing for active medical device:

- IEC 60601-1
- Functional safety
- Cybersecurity
- IEC 62304 Medical device software
- NRTL testing
- IECEE CB Scheme
- INMETRO testing for electrical medical devices
- EMC testing
- Environmental testing
- ISO 14971 Risk management requirements for medical devices

…but when does testing take place?

V-Model

Documentation model



High Level Design Development Activities

Testing related

Definition & Planning	Design & Development	Verification & Validation	Commercialization
High Level System Design	Detailed Design and Development Testing	System Verification	Market Launch
Evaluate Feasibility	Engineering Model Evaluation	Regulatory & Standards Approval	Post market activities
Design Requirement Specification	V&V Planning	Design Validation	Global market Launch
	Engineering Model	Submit for Regulatory Approvals	
	System Design V&V Preparation	Design Verification Model / Pilot Model	

Design Input

- functional, performance and safety requirements of a product

- capture, analyze, and interpret the needs and requirements of
  - external users
  - internal users
  - regulatory bodies

- Following are Design Inputs:
  - translated user needs
  - system design,
  - subsystem design,
  - and/or regulatory requirement

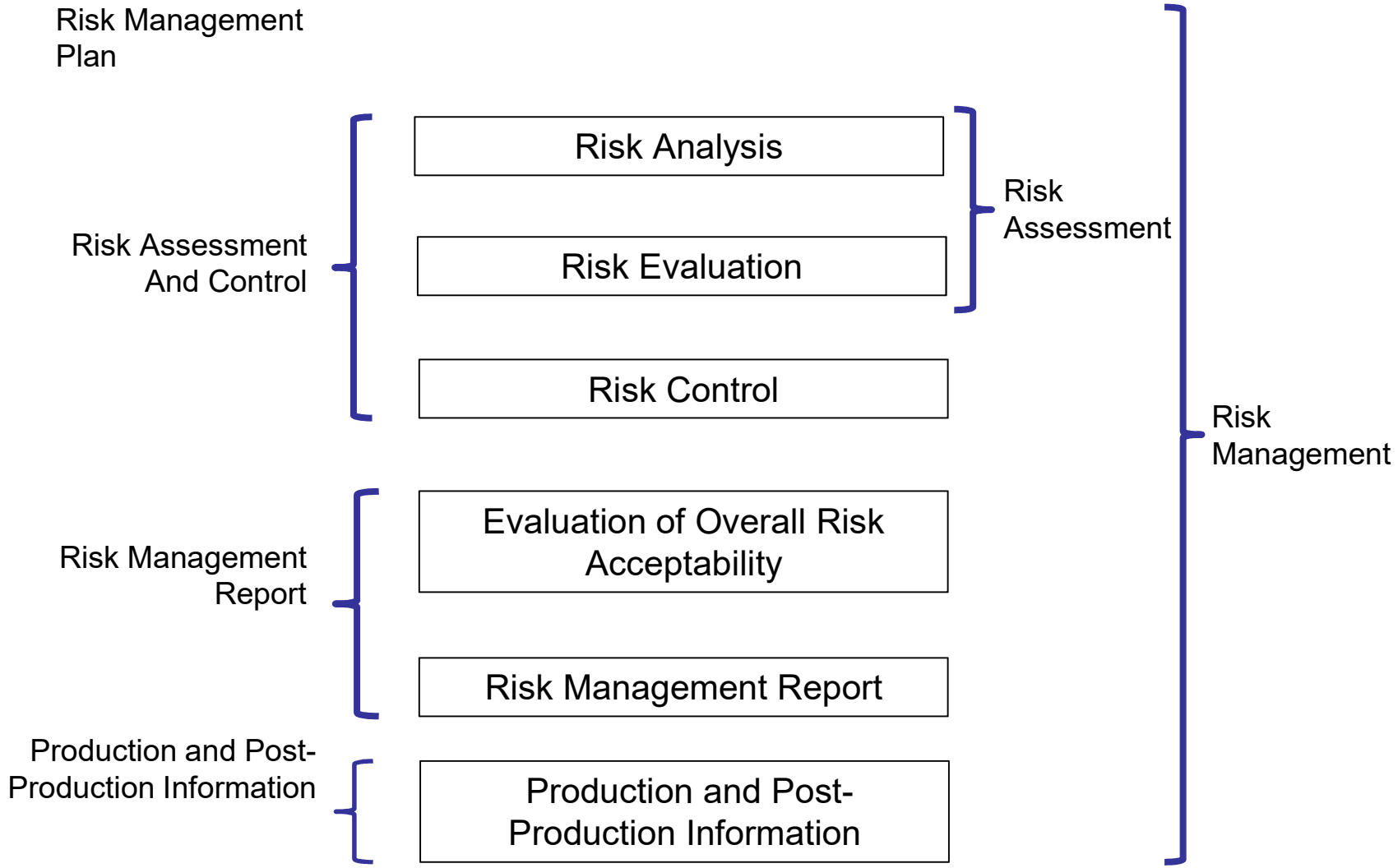
→ Addresses the intended use of the product

Example for Design input documentation

- User requirements specification
- Design requirement specification
- Hardware detailed design
- First risk assessment
- D&FMEA
- Intended of Use
- System Architecture
- Codes & Standards Verification Plan
- global target markets for selling
- Insulation coordination concept
- Functional safety concept
- Cybersecurity concept
- List of applicable code & standards
- battery requirements for product certification
- air-creepage distances
- MOPP / MOOP definition
- Degree of contamination
- operation altitude

Risk Management Process / ISO 14971

Risk Management is Design Input



Medical Electrical Equipment: General Requirements for Safety

Example: Clauses from standards requiring Testing & Verification

Test	Clause	Test Description
[ ]	4.11	Power Input Test
[ ]	5.7	Humidity Preconditioning Treatment
[ ]	7.1.2	Legibility of Marking Test
[ ]	7.1.3	Durability of Marking Test
[ ]	8.4.2	Low Voltage Reliability
[ ]	8.4.3	Voltage or Charge Limitation
[ ]	8.4.4	Voltage Limitation (Part 2)
[ ]	8.5.4	Working Voltage Measurement
[ ]	8.5.5	Defibrillation-Proof Applied Parts
[ ]	8.5.5.2	Defibrillation-Proof Applied Parts (Energy Reduction Test)
[ ]	8.6.4a	Earthing and Potential Equalization Test
[ ]	8.7	Leakage Current Test
[ ]	8.8.3	Dielectric Voltage Withstand
[ ]	8.8.4.1	Ball Pressure
[ ]	8.9.2	Short Circuiting in Lieu Creepage Distances and Air Clearance
[ ]	8.9.3	Thermal Cycling Test for Spaces Filled by Insulating Compound
[ ]	9.2.2.2	Measurement of Gaps (e.g. Finger and Foot Measurement)
[ ]	9.4.2	Stability and Transportability
[ ]	9.4.2.4.2	Mobile Equipment Force for Propulsion Test
[ ]	9.4.2.4.3	Mobile Equipment Movement Over a Threshold
[ ]	9.4.3.1	Instability from Unwanted Lateral Movement
[ ]	9.4.3.2	Instability Excluding Transport
[ ]	9.6.2.1	Acoustic Energy Measurement
[ ]	9.6.3	Hand Transmitted Vibration
[ ]	9.7	Hydrostatic Pressure Test

Design Inputs from standards

Example IEC 60601-1

RATED operating altitude (*a*) m	Normal barometric pressure kPa	Multiplication factor for MOOP	Multiplication factor for MOPP
$a \leq 2\,000$	80,0	1,00	1,00
$2\,000 < a \leq 3\,000$	70,0	1,14	1,00
$3\,000 < a \leq 4\,000$	62,0	1,29	1,14
$4\,000 < a \leq 5\,000$	54,0	1,48	1,29

Air clearance for altitudes e.g. La Paz / Bolivian / South American > 3500 m

WORKING VOLTAGE V d.c. up to and including	WORKING VOLTAGE V r.m.s. up to and including	Spacing providing ONE MEANS OF PATIENT PROTECTION		Spacing providing TWO MEANS OF PATIENT PROTECTION	
		CREEPAGE DISTANCE mm	AIR CLEARANCE mm	CREEPAGE DISTANCE mm	AIR CLEARANCE mm
17	12	1,7	0,8	3,4	1,6
43	30	2	1	4	2
85	60	2,3	1,2	4,6	2,4
177	125	3	1,6	6	3,2
354	250	4	2,5	8	5

Creepage distances and air clearances

→ standard requirements, also design Input requirements !

Design Output

- results of the design and engineering efforts
- documented in models, drawings and other documents
- design specifications that allow an
  - adequate evaluation of conformance to design input requirements,
  - as confirmed during design verification and validation and ensured during design reviews.
  - acceptance criteria

- Design outputs are:
  - Final specifications for the device
  - Part Drawings
  - Specification documents
  - Production and Quality assurance specification and process
  - Manufacturing method and inspection process

Example for Design Output Testing

- Risk control measures implementation
- Testing of subsystems, modules and EMC
- electrical safety testing e.g. leakage current, high voltage
- safety testing
- EMC testing
- Environmental testing
- battery testing
- Product performance testing
- functional safety
- Formative usability studies
- Cybersecurity testing

Design Verification

- confirmation by
  - examination and provision of objective evidence that specified requirements (design inputs) have been met

- The results of design verification are
  - controlled and contain methods
  - dates and names of employees who performed the design verification

→ Test documentation & Reports

Design Validation

- objective evidence that product specifications conform to defined user need requirements and intended use(s)

- Design validation is performed with defined operating conditions on
  - initial production units, lots, batches, or their equivalent under actual or simulated use conditions

- Design validation will include, where appropriate
  - software validation and risk analysis

- The results of design validation are controlled and contain
  - identification of the design,
  - methods,
  - dates, and
  - names of employees who performed the design validation.

Examples for Product V&V Testing

Basic safety standards

- 2nd Edition of IEC 60601-1 (IEC 60601-1:1988 + A1:1991 + A2:1995)
- 3rd Edition of IEC 60601-1 (IEC 60601-1:2005)
- 3.1 Edition of IEC 60601-1 (IEC 60601-1:2005 + A1:2012)

Collateral standards

• EMC Testing	IEC 60601-1-2 / 3rd Edition 4th Edition
• Usability evaluation	IEC 60601-1-6 & IEC 62366
• Alarm system	IEC 60601-1-8
• Environmentally Design	IEC 60601-1-9
• Closed Loop controllers	IEC 60601-1-10
• Home Healthcare Environment	IEC 60601-1-11
• Emergency Environmental	IEC 60601-1-12

Particular standards	Software
• IEC 60601-2-x	IEC 62304

Testing after Commercialization

- Testing of national deviations
- product registration
- Radio approval Registration and Tests
- Product Certification
- e.g. INMETRO, ANATEL, FCC, IC
- re-testing after a change
- impact analysis after change
- re-issue CB/ NRTL certification

Examples for Global Market Testing

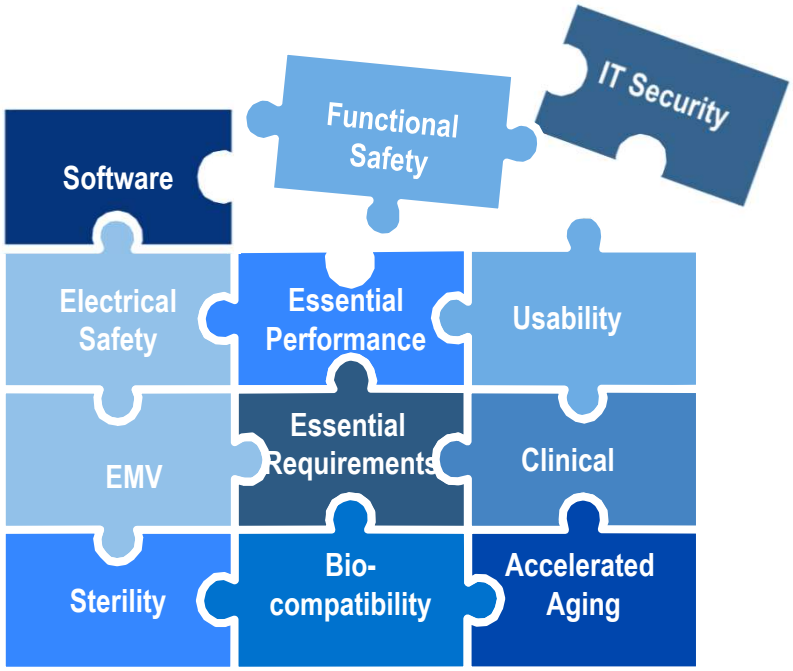
IEC 60601-1 National Deviation testing

– USA	I/AAMI ES 60601-1)
– Canada	(CAN/CSA C22.2 No. 60601-1)
– Korea	(KSC C IEC 60601-1)

Radio equipment testing & country registration

– Europe	RED
– USA	FCC
– Canada	IC
– Brazil	ANATEL
– Taiwan	LP002
– Japan	MIC
– South Korea	KCC

Overview



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CE-Marking vs. Certification Mark

- Legal requirements
- No certification mark, but: marking for the authorities
- Consumer products: at least 85% manufacturer self-declaration
- Product meets requirements of the guidelines
- No production monitoring by independent third party
- Where CE is not required by law, this labelling is prohibited

They are worlds apart

By an independent third party

- Voluntary certification
- The product is safe → added value
- Continuous production monitoring

Testing Procedures

	Result	Requirements from	Documentation for
Voluntary Testing	Technical Report, Test Report Files based on Standards	ISO 17025	European Market, international Market
CB	CB Certificate + Test Report Files	IECEE (incl. ISO 17025)	International Market
NRTL	NRTL Certificate + Test Report Files	OSHA and SCC (incl. ISO 17025)	USA / Canada Market
TÜV Mark	TÜV Certificate + Test Report Files	TÜV SÜD (incl. ISO 17025)	International Market and European Market
DAkkS	Test Report Files	DAkkS (incl. ISO 17025)	European Market
ILAC	Test Report Files	DAkkS (incl. ISO 17025)	Brazil Market

What is accreditation according to ISO 17025?

- Reliability through conformity assessments

- Accreditation ensure that
  - tested products,
  - methods
  - services or systems

- reliable with regard to
  - quality and safety,
  - correspond to a technical minimum standard
  - conform to the standards, guidelines and laws that correspond with the various requirements.

What shows accreditation according to ISO 17025?

- technical competence
- compliance with statutory and standards-based requirements
- internationally comparative standard
- monitors the management system
- competence of assigned personnel
- comparability of conformity assessment results
- Creating trust in the quality and safety

What is “Certification”?

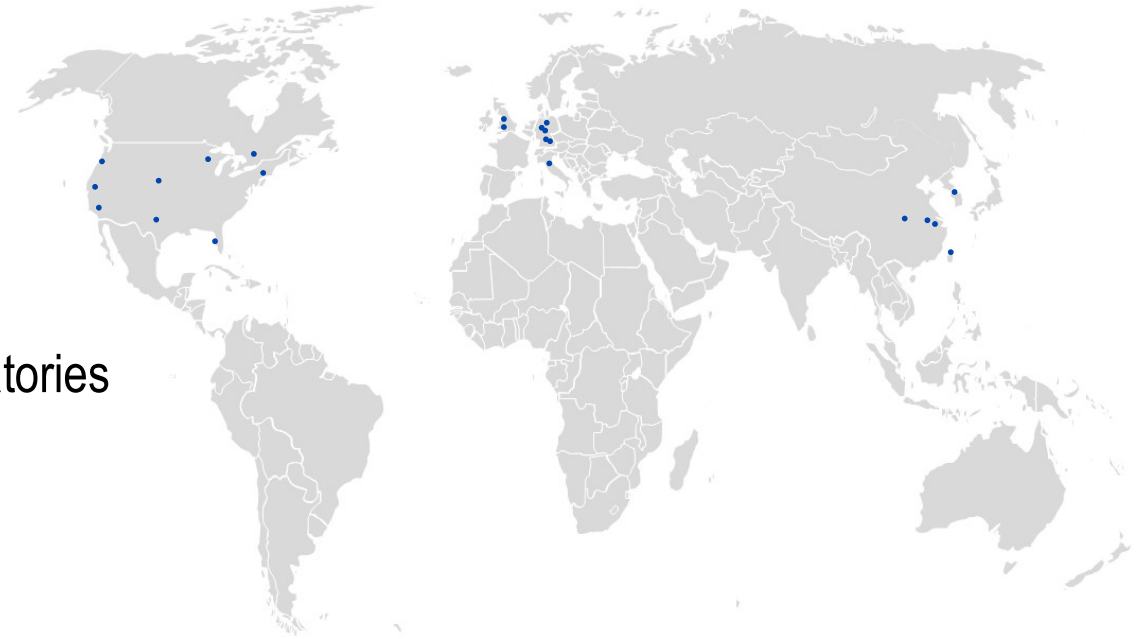
Certification is defined:

- written authorized confirmation
- by an independent "third" body
- For a product (or a QM system)
- on the basis of a product evaluation
- confirmation of the fulfilment of specified normative requirements

IECEE: What is the CB Scheme?

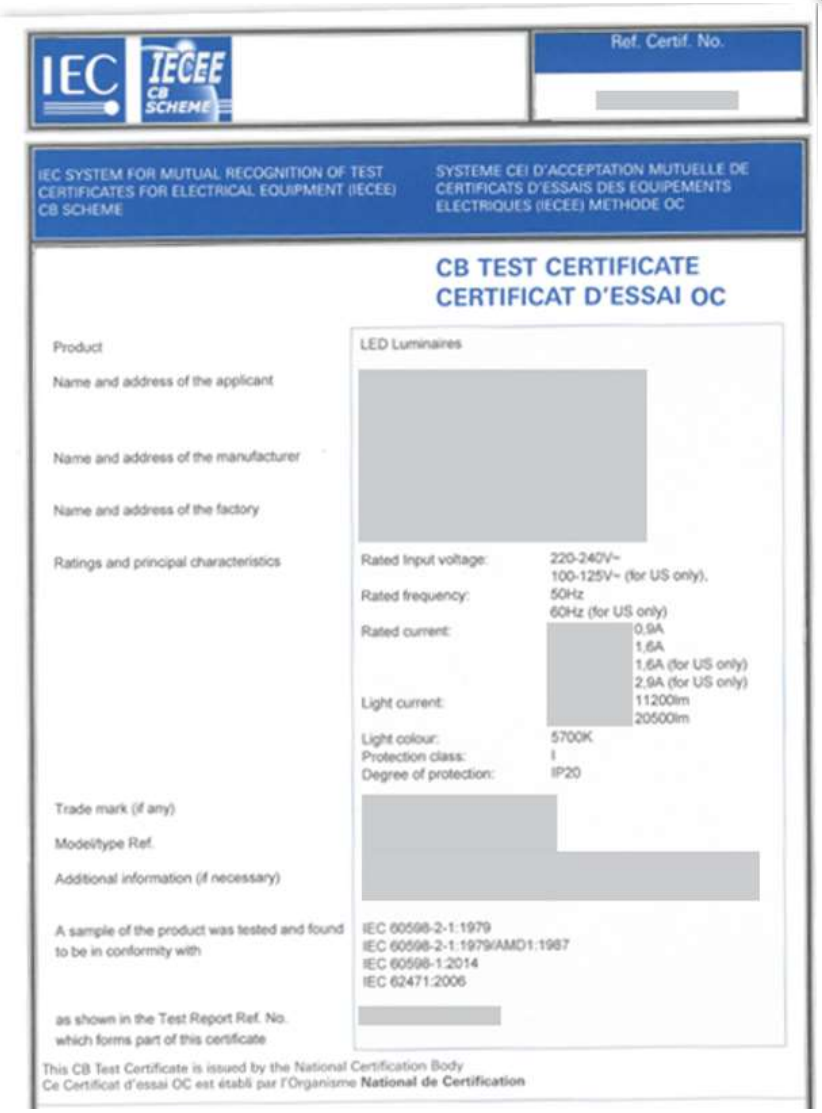
- Multilateral certification system for electrical equipment and components
- Based on international IEC standards
- „National Deviations“ can be considered
- Worldwide, mutual recognition of certificates by all members in the CB Scheme

Worldwide 24 CB Test Laboratories
of TÜV SÜD Product Service



IECEE: CB Certificate

- Voluntary certificate without certification mark
- Testing according to standard conformity
- Test reports can serve as a basis for further certifications (national certification procedures)
- Testing of a single sample, no production monitoring



IEC IECEE CB SCHEME

Ref. Certif. No.

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product	LED Luminaires
Name and address of the applicant	
Name and address of the manufacturer	
Name and address of the factory	
Ratings and principal characteristics	Rated Input voltage: 220-240V~ 100-125V~ (for US only), Rated frequency: 50Hz 60Hz (for US only) Rated current: 0.9A 1.6A 1.6A (for US only) 2.9A (for US only) Light current: 11200lm 20500lm Light colour: 5700K Protection class: I Degree of protection: IP20
Trade mark (if any)	
Model/type Ref.	
Additional information (if necessary)	
A sample of the product was tested and found to be in conformity with	IEC 60598-2-1:1979 IEC 60598-2-1:1979/AMD1:1987 IEC 60598-1:2014 IEC 62471:2006
as shown in the Test Report Ref. No. which forms part of this certificate	

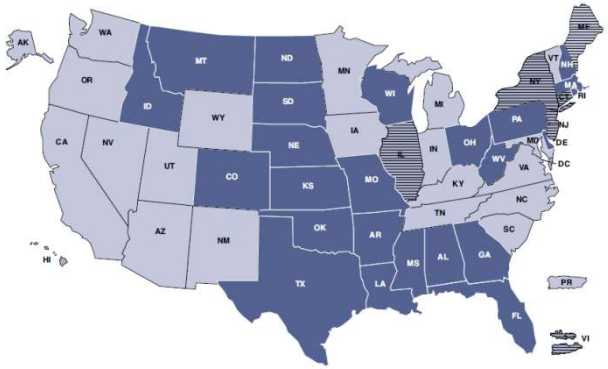
This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

Nationally Recognized Testing Laboratories (NRTL)

- In 1970, the United States Congress and President Richard Nixon created the Occupational Safety and Health Administration (OSHA), a national public health agency dedicated to the basic proposition that no worker should have to choose between their life and their job.

- Mission of OSHA: Congress created OSHA to assure safe and healthful conditions for working men and women by setting and enforcing standards and providing training, outreach, education and compliance assistance.

- www.osha.gov



Nationally Recognized Testing Laboratories (NRTL)

Global Market Testing & Certification

TÜV SÜD America Inc.

10 Technology Drive
Peabody, Massachusetts 01960
United States
Phone: 978-739-7000
Fax: 978-762-8414
Docket Number: OSHA-2007-0043
Certificate (PDF)
Web Site
Certification Listing Web Site
Certification Mark Web Site

Scope of Recognition*

Recognized Testing Sites

Recognized Testing Standards

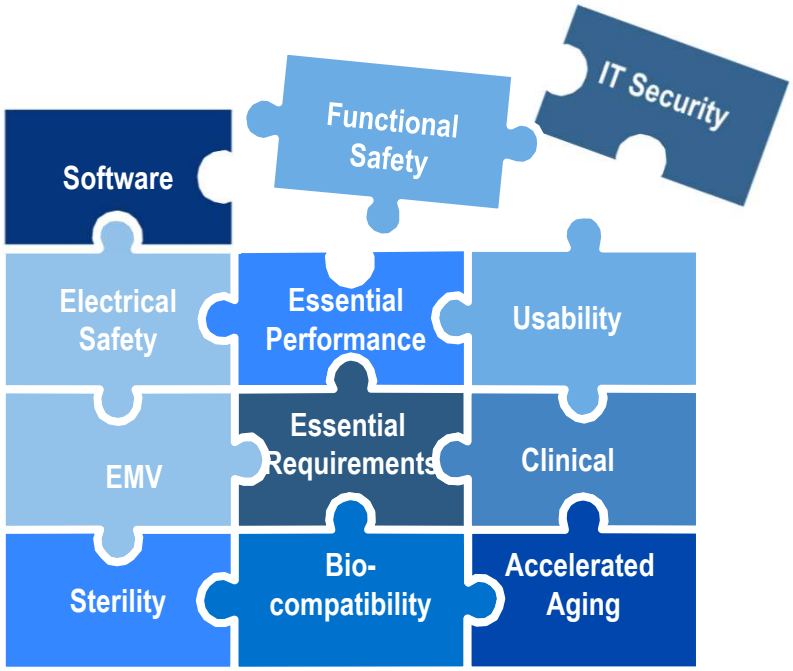
ANSI/AAMI ES60601-1:2005/(R) 2012	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (with amendments)
ANSI Z21.13	Gas-Fired Low Pressure Steam and Hot Water Boilers
ANSI Z21.10.3	Gas-Fired Water Heaters - Volume III, Storage Water Heaters With Input Ratings Above 75,000 BTU Per Hour, Circulating and Instantaneous
ANSI Z83.8	Gas Unit Heaters, Gas Utility Heaters and Gas-Fired Duct Furnaces
UL 22	Amusement and Gaming Machines
UL 48	Electric Signs
UL 50	Enclosures for Electrical Equipment
UL 67	Panelboards
UL 69	Electric Fence Controllers

Nationally Recognized Testing Laboratories (NRTL)

Summary:

- NRTL is a type testing of the device (Test Reports, Data Form) with a factory inspection
- Some Governments or public hospitals from USA could request a NRTL Certificate for a medical product
- 3rd Party evidence from NRTL which are listed on the OSHA-website
- Covers the applicable test standard of the relevant country (US and/or Canada)
- NRTL is implemented according to the OSHA regulation 29 CFR 1910.7.

Overview



Medical Product Testing

Design Input
Technical Documentation Assessment

- **Scope of Tests**
  - design input requirements based on Codes & Standards
- **Deliverables by the manufacturer**
  - Design Input documents e.g. Design Requirement Specification, User Requirements Specification, Hardware Detailed Design, Risk Management File, FMEA, Intended of Use, System Architecture, Codes & Standards Verification Plan, Functional safety concept, global target markets for selling
- **Deliverables 3rd Party Test Lab**
  - Review based on codes and standards requirements

Design Output
Development Testing

- **Scope of Tests**
  - testing / subclause testing and spot-checks based on design Input requirements according to Phase 1
- **Deliverables by the manufacturer**
  - Update of Design Input documents and test samples e.g. First mock-up, prototypes, engineering samples, power supplies, batteries, modules, sub-components, first drafts of accompanying documents, risk management file, usability, software documentation
- **Deliverables 3rd Party Test Lab**
  - test reports based on performed tests (safety, EMV, ENV), measurements e.g. on first mock-up, prototypes, draft documentation

Medical Product Testing

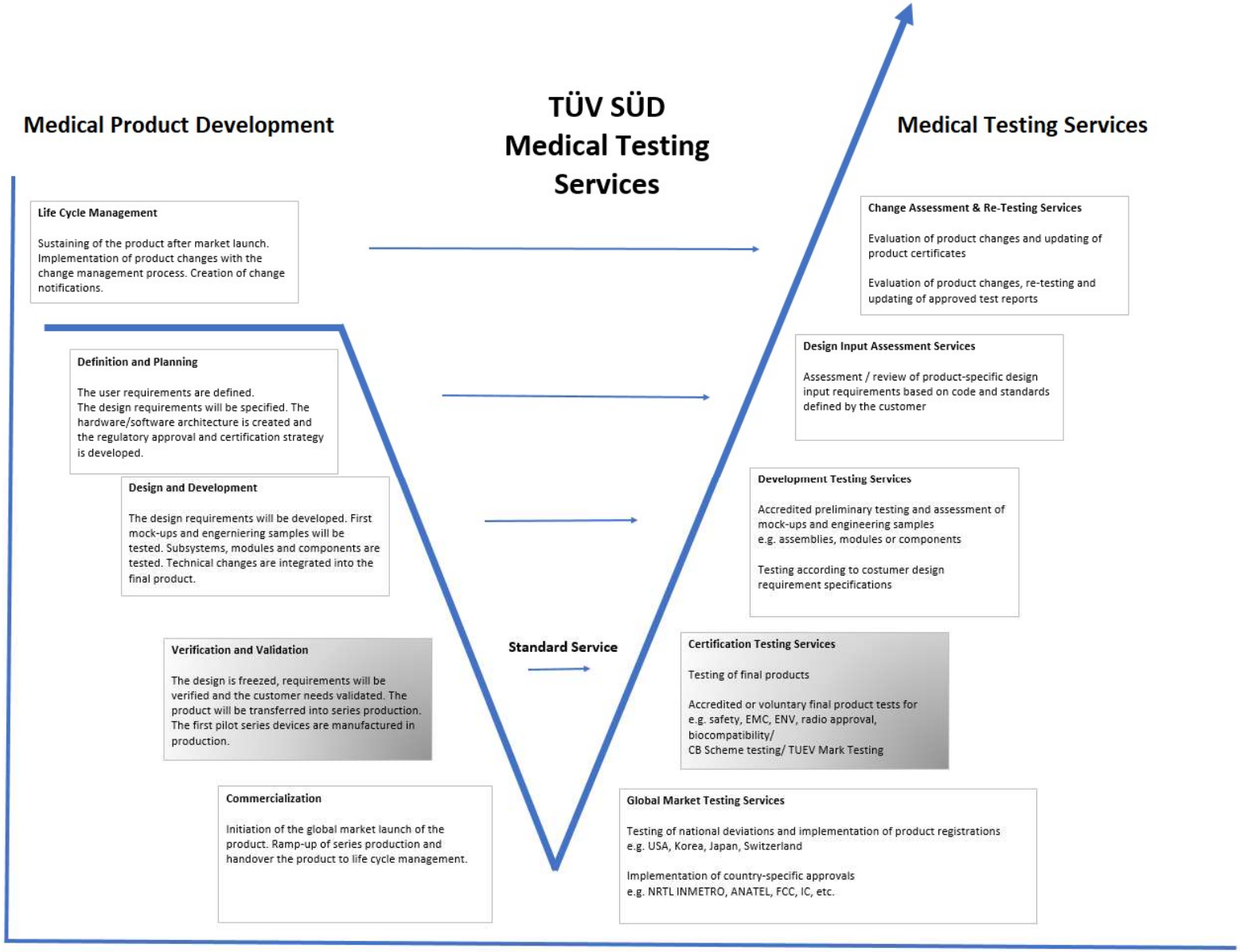
Verification/ Validation Certification Testing

- **Scope of Tests**
  - Accredited final product certification/ testing for e.g. safety, EMC, ENV, Radio Approval
- **Deliverables by the manufacturer**
  - Final release of Technical documentation, pilot series test samples e.g. Risk Management File, Usability File, Software documentation, drawings, circuit diagrams, instruction for use
- **Deliverables 3rd Party Test Lab**
  - CB-Reports and certificates / voluntary test reports according to DAkkS scope, CB Scheme

Commercialization Global Market Testing

- **Scope of Tests**
  - Testing of national deviations and extend international requirements
- **Deliverables by the manufacturer**
  - Final Test Reports, Test samples, Updated final released technical documentation e.g. Risk Management File, Usability File, Software documentation, drawings, circuit diagrams, instruction for use
- **Deliverables 3rd Party Test Lab**
  - Deviation Reports, NRTL certificate, ILAC Reports, INMETRO, ANATEL, FCC and letters for authorities

TÜV SÜD Medical Testing Services



Product Service

Mehr Sicherheit.
Mehr Wert.

Umfassender Service – aus einer Hand!

Dipl.-Ing (FH)

Rouven Rosenheimer

Senior Account Manager

Rouven.Rosenheimer@tuev-sued.de

Phone:+49 89 5008-4782

Weitere Informationen:

www.tuev-sued.de/ps