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Regulatory

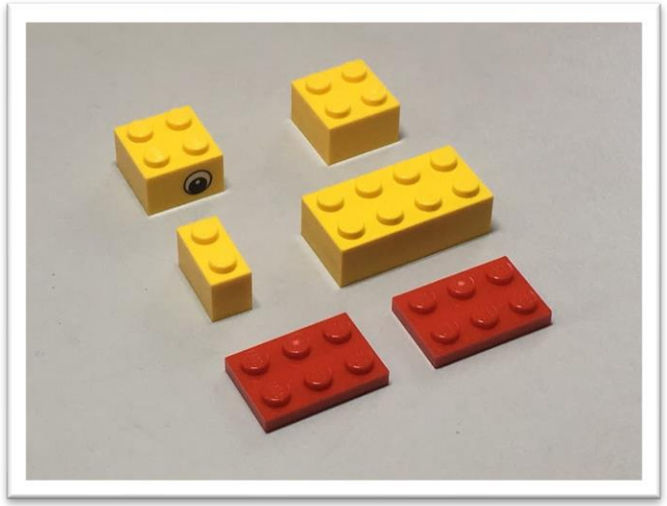
Innovation in an existing medical device

the impact of changes on development, manufacturing and regulatory processes

MEDISCHE ELEKTRONICA
Ontwikkelingen, normen en toepassingen

6 februari 2024 | Van der Valk Vianen

Changes: be creative, be efficient, look ahead!



WHY

and

HOW

Source: http://www.legoengineering.com/build-a-duck/

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Overview

- Introduction Unitron
- The various layers of medical device compliance
- The impact of changes - a practical case
- Change process
- Design, Regulatory and manufacturing impact
- Conclusions

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Introduction

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Development and production of medical equipment and tools

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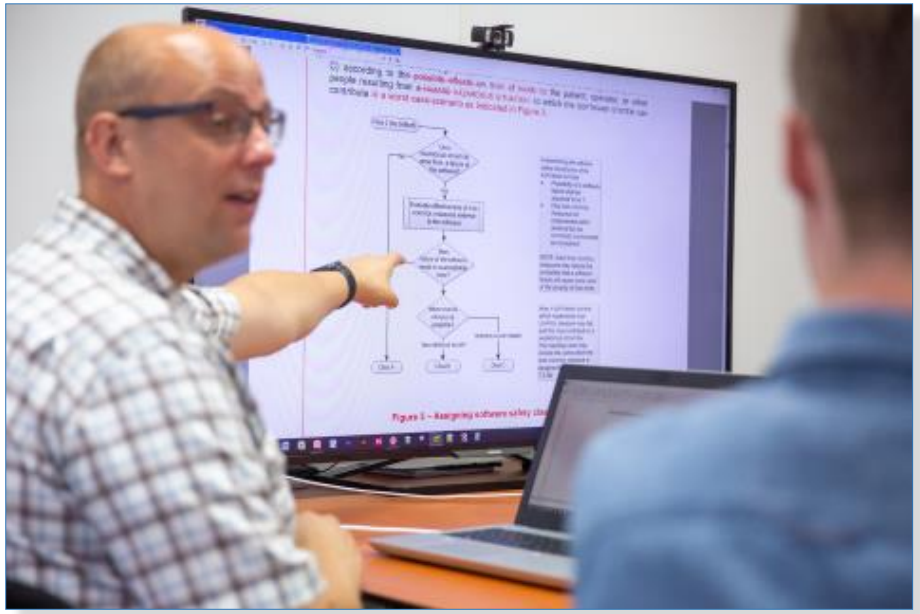
Regulatory

Advice and support for certification and regulatory compliance



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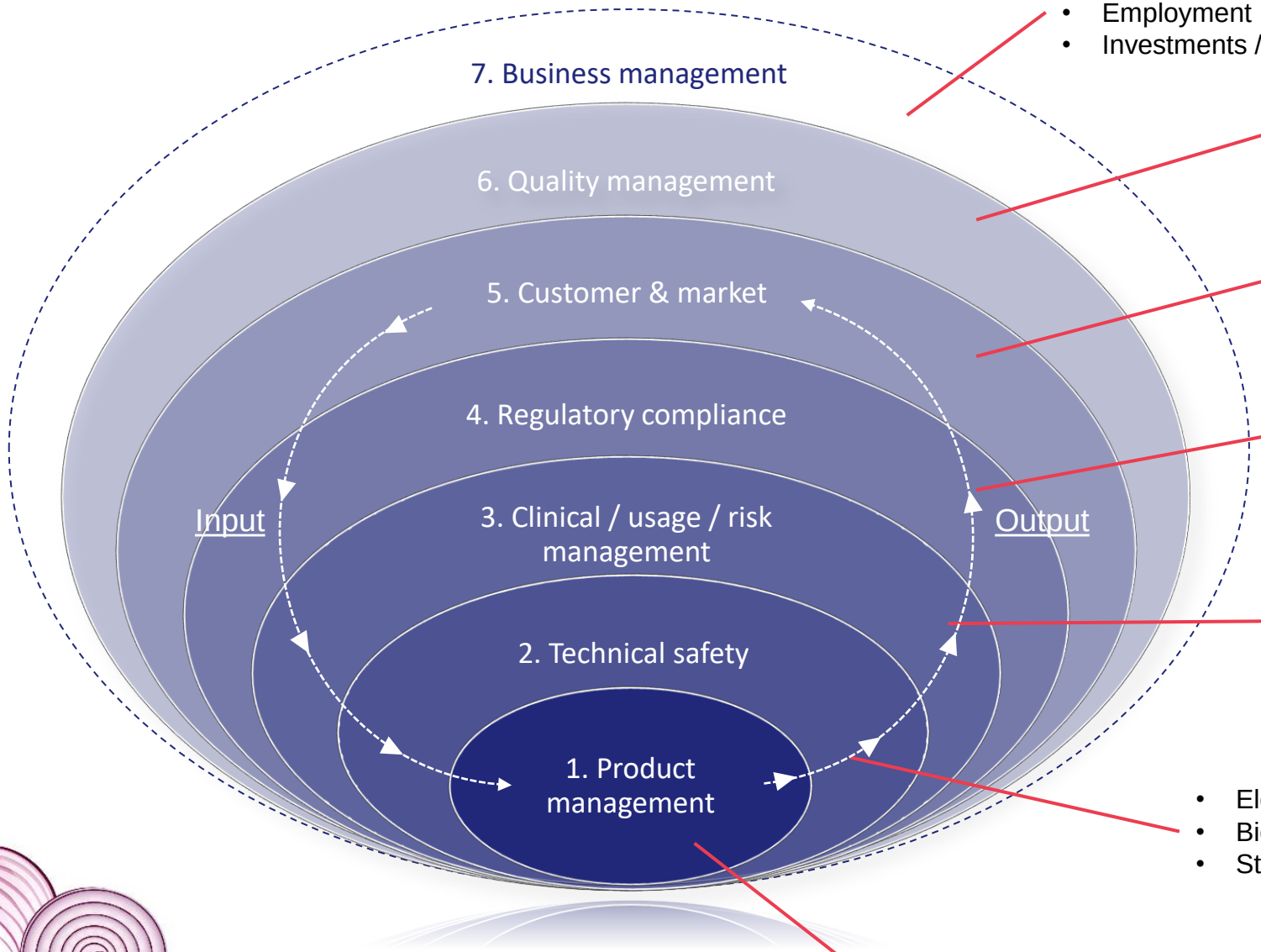
The various layers of medical device compliance



- Business establishment, mission, vision, etc.
- Employment
- Investments / finance management

- QMS, ISO 13485

- User needs
- Market identification
- Post-market surveillance

- EU-MDR, US-FDA
- Notified Body approval

- Intended purpose
- Clinical claims / evaluation
- Usability
- Risk management

- Electrical safety
- Biological safety
- Sterilization & shelf life

- Design and development
- Product quality and technical performance
- Manufacturing quality and reliability

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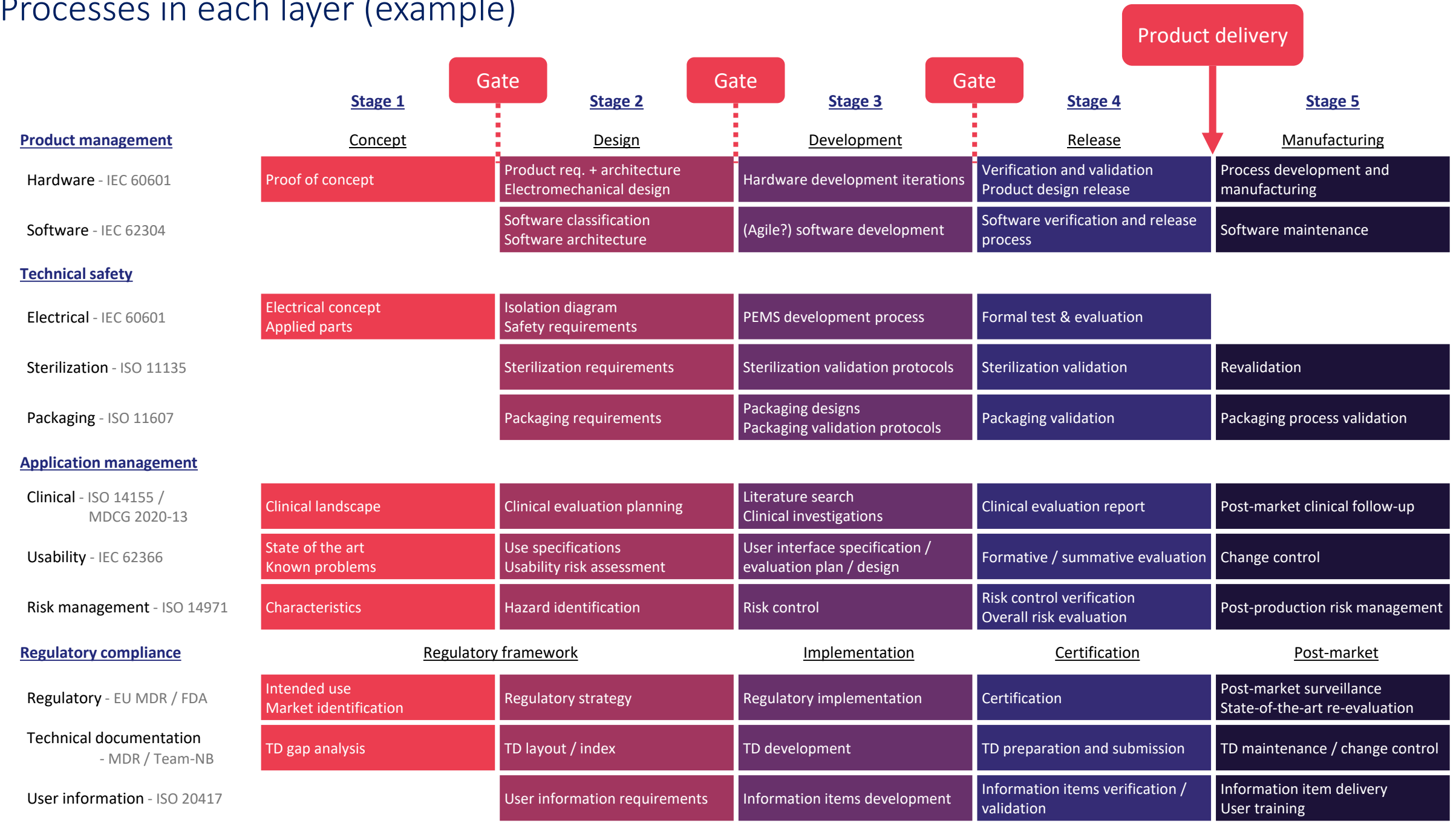
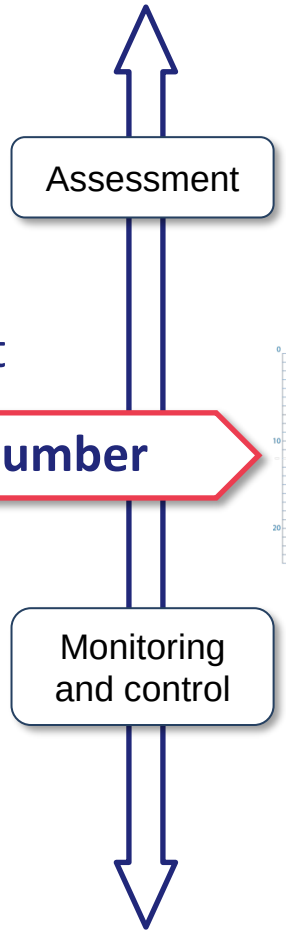
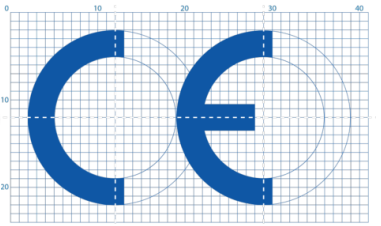
Processes in each layer (example)



Change impact per product stage

Stage	Change impact field
1. Product design	Component / material selection
2. Verification / validation	Test reports, critical components
3. Design transfer	Manufacturing process design and validation
4. Clinical / use evaluation	Clinical evaluation, usability study, risk management
5. Certification (NB)	**Product + QMS assessment => CE certificate + NB number**
6. Manufacturing	Quality management system, audits, suppliers
7. Handling and use	Labeling, user information, packaging, transport
8. Post-market	PMS, notifications to Notified Body
9. Life cycle	Repair, service, traceability





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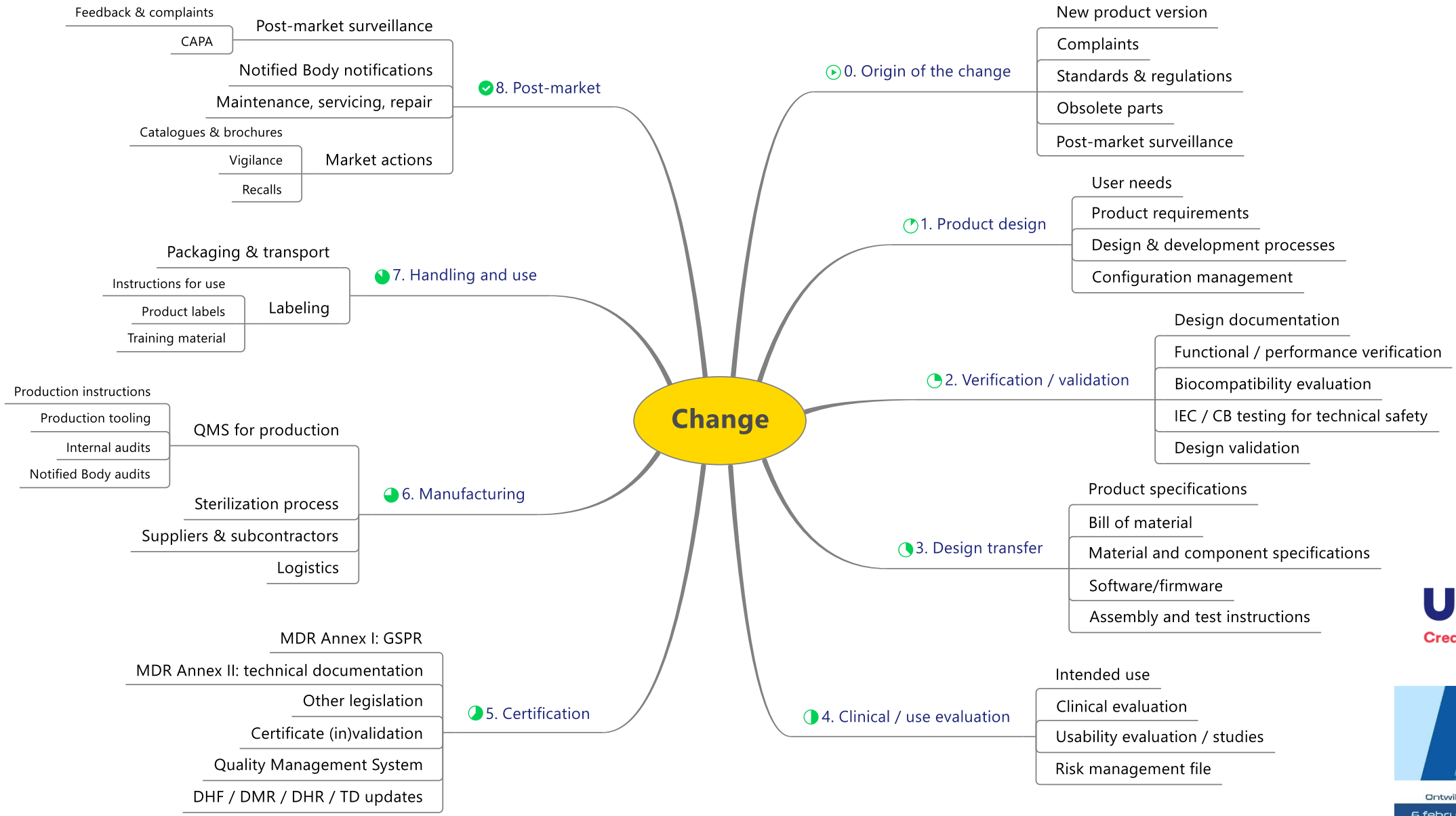
Change impact per product stage - mindmap



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Change process

1. Impact analysis
   - Which parts, components or materials are affected? => configuration management
   - Which areas of documentation are affected?
   - Which processes are affected?
   - Which approvals are affected?
2. Rationalise why the change is needed and acceptable (involve test lab)
3. Controlled product + documentation change process
   - Go back in the product development / life cycle processes as far as necessary
   - Update the DHF, DMR, DHR and TD
   - Don’t forget to update the risk management file and (end) user information
4. Assessment by Notified Body
   - ‘substantial’ => via change notification / renewed certificate
   - not ‘substantial’ => via regular audit

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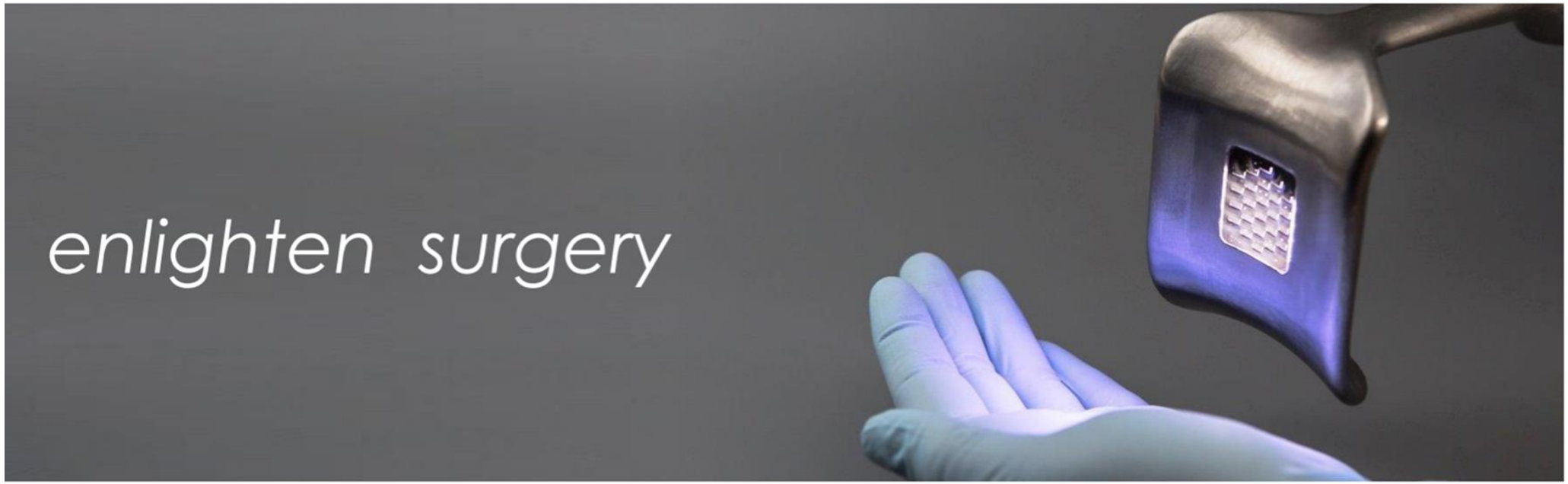
Changes in a medical device

ILLUMI

SURGICAL



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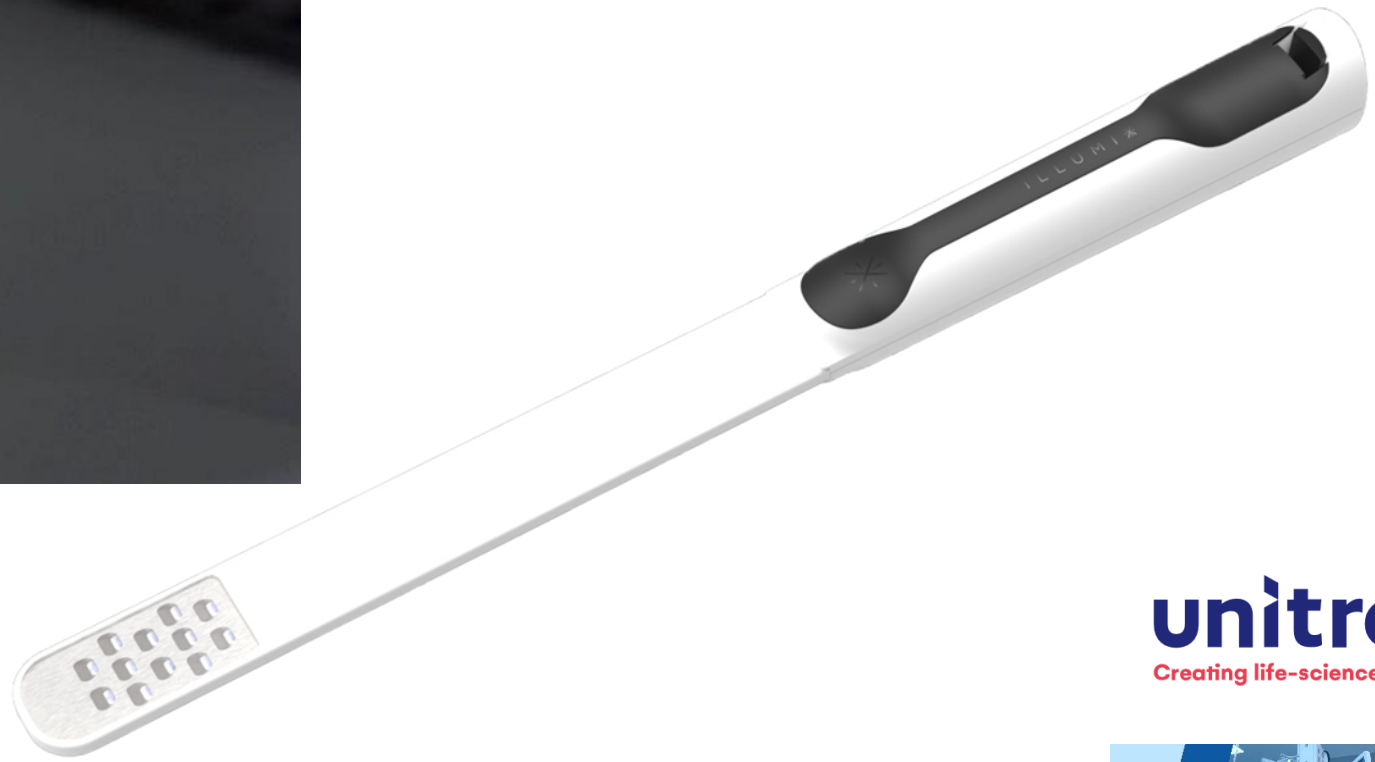
SOLUTION: ILLUMIX

Optimal lighting and superior ergonomics during surgery

- Light where needed
  - Self contained, built in battery
  - Directs light where it is needed
  - Eliminates or minimizes backscatter light
  - Single use capabilities
- Optimal ergonomics
  - Reduces fatigue for operators



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Changes – impact analysis

- ✓ Scope and use of device
- ✓ Versions to launch, marketing strategy
- ✓ Biocompatibility (surface area) and correct classification of device
- ✓ Sterilisation method
- ✓ Temperature stability
- ✓ Color temperature
- ✓ Requirements
- ✓ Risk Management
- ✓ Packaging
- ✓ Purchasing

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Changes – impact analysis

✓ Scope and use of device	Different operating field
✓ Versions to launch, marketing strategy	Several strategies, depending on distributor
✓ Biocompatibility (surface area) and correct classification of device	Larger blade
✓ Sterilisation method	Same sterilization method but bigger plant
✓ Temperature stability	More LEDS
✓ Color temperature	Change of LEDS
✓ Requirements	
✓ Risk Management	
✓ Packaging	Change of packaging, marketing strategies
✓ Purchasing	Change of supplier

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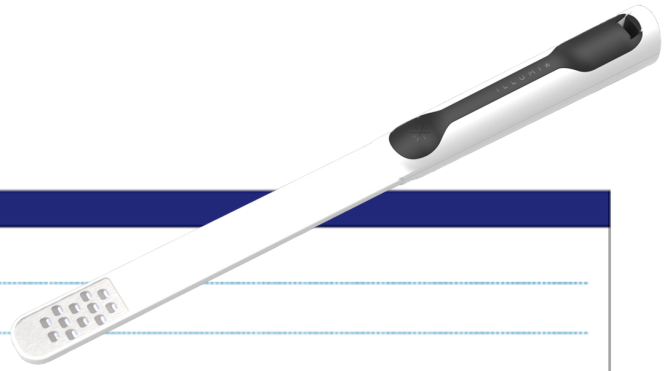
Product Delivery

	Concept innovation			Design iterations			Go to and production		And beyond	
	Definition	Concept	Detailing	Engineering	Proto	Verification	Transfer	Qualification	Service	PLM
Development	Context & Architecture	Detailed Architecture	Proof of concept	Design TOI & integration	Alpha Beta	Verification Tech Doc.	Technical Documentation		Support	PLM proposal
Usability	Site visit interview	End user concept		User feedback		Validation			PMS interview	PLM input
Technology	Tech research FTO & New IP			Tech detailing		Filling IP			Maintain IP	New technology
Quality	Project Risk analysis Specifications		Gate review	Design History File		Gate review	STED file	Gate review	QMS	ECO RMA
Regulatory		Certification framework		Process review NB Consulting			Regulatory submission Q&A till approvel			
Manufacturing			Evaluation PoC	DFM	Beta	Verification	PFMEA Process	IQ, OQ, PQ, Master Validation Report	SLA maintenance	PLM input
Supply chain		Strategic sourcing		Strategic sourcing	Tooling	Verification	Sample orders	Quality agreement	Cost optimization	PLM input

Change process



DESIGN CHANGE EVALUATION

<CUSTOMER> | <PRODUCT> | DESIGN CHANGE

CHANGE DESCRIPTION

Name Initiator:	<Name>	**Creation Date:**	<dd-MMM-yyy
Medical Device:	YES	**Change status:**	NEW

Purpose:

This document is intended to identify, track and approve changes to any change-controlled document and design and development process, and to evaluate the impact of these changes.
The intended audience are the parties included in the review and approval section.

Reason of change:

Add a description of the reason for the change.
if applicable, add a reference (to a report, review, e-mail, meeting minutes or issue registration)

Description of change:

Add a description of the change

REVIEW AND APPROVAL

Name	Role	Organisation	Date (dd-MMM-yyyy)	Signatu
	Project Leader	Unitron		
	Lead Engineer	Unitron		
	Customer representative	<Customer>		

IMPACT ANALYSIS

Project Management evaluation:

Evaluate the impact of the change in regards of the following topics:

Lead time / planning (project plan): applicable: NO
…

Budgets / financial agreements: applicable: NO
…

Parts or materials already ordered or delivered: applicable: NO
…

Other: applicable: NO
…

Technical evaluation:

Evaluate the impact and significance of the change in regards of the following topics:

Function, Performance or Usability: applicable: NO
…

Safety / Risk management: applicable: NO
…

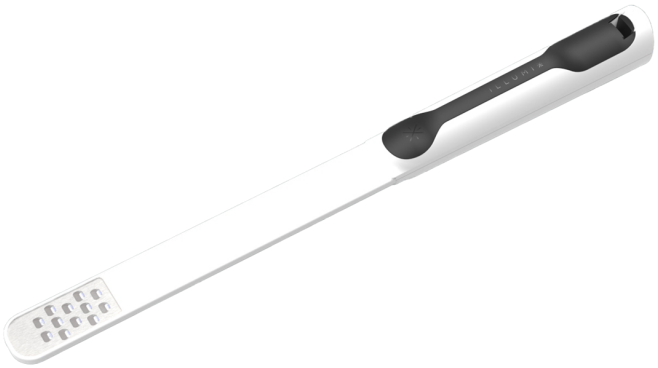
Regulatory Aspects: applicable: NO
…

Requirements: applicable: NO
…

Verification activities: applicable: NO
…

Other: applicable: NO
…

Change process



Change document

1. RFC information and status

Subject	<Subject>		
Name initiator	<Your name>	**Function**	
Creation date (dd-mmm-yyyy)			
Product(s)	[Product]	**Product / part nr.**	
Medical device	Yes		
Originator		**Contact Person**	
Reason for proposed change(s)			
Description of proposed change(s)			
Benefit(s) of change			
Impact assessment			

An impact assessment of this change has been performed to identify any new risks, significantly modified existing risks and impact on documentation and/or processes. This assessment will results in actions to be taken.

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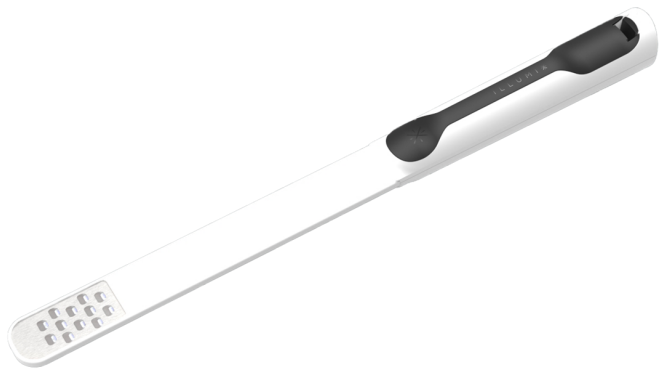
Change process

Significance of change:

-Impact process risk analysis
-Impact validation master plan/report:
-Impact production processes and documentation:
-Calibration and Maintenance
-Purchasing, stock and logistics:
-Sales

The legal manufacturer / customer



e.g.

- Perform ECO
- Create BOM(s) + BOM approval
- Create new Unitron part numbers for
- Link updated drawings/documentation/etc to new Unitron part numbers
- Increase BOM revisions
- If an item number has been incremented, check whether the old item number has chang

in all parts lists (Where used function in Omnify).

- Update Critical component verification document
- Update Bom pcba report
- Update SMT Verification protocol / Report
- Update MES
- Update production history sheets
- Update Product / PCBA / subassy labeling
- Update/create work instructions and DHRs
- Update and link Inspection Sheet documents (VIS)
- Update picking BOM database
- Check DHR & CoC
- Update/create maintenance instruction
- Update process flow
- Training of operators
- Update work station
- Update job(s)
- Update Technical File + share if applicable
- Update “Procestijden” sheet F-704
- Rework according to rework instruction
- Spareparts + check instructions for correct references to drawings / specifications
- Synergy ‘voorraad verrekening klant’
- Update Kanban
- Adapt ongoing orders
- …….

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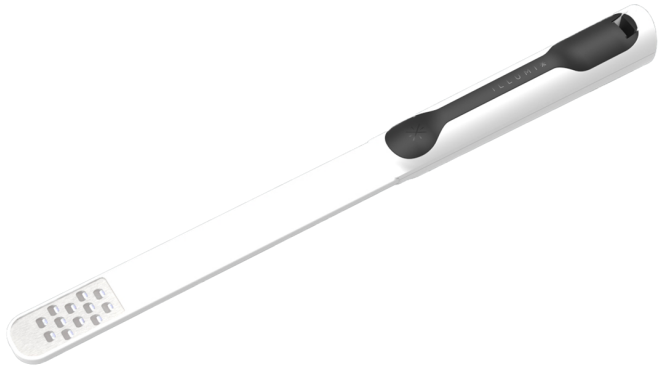
Changes – technical documentation



- MDR Annex II (and III)
- Complete before certification, change control after certification

1. General aspects
2. Device description
3. Risk management
4. Essential requirements
5. Performance verification
6. Electrical safety & EMC
7. Usability
8. Software
9. Sterilization
10. Packaging & shelf life
11. Biocompatibility
12. Clinical evaluation
13. Manufacturing information
14. Labeling
15. Animal tissue
16. Drug device combinations

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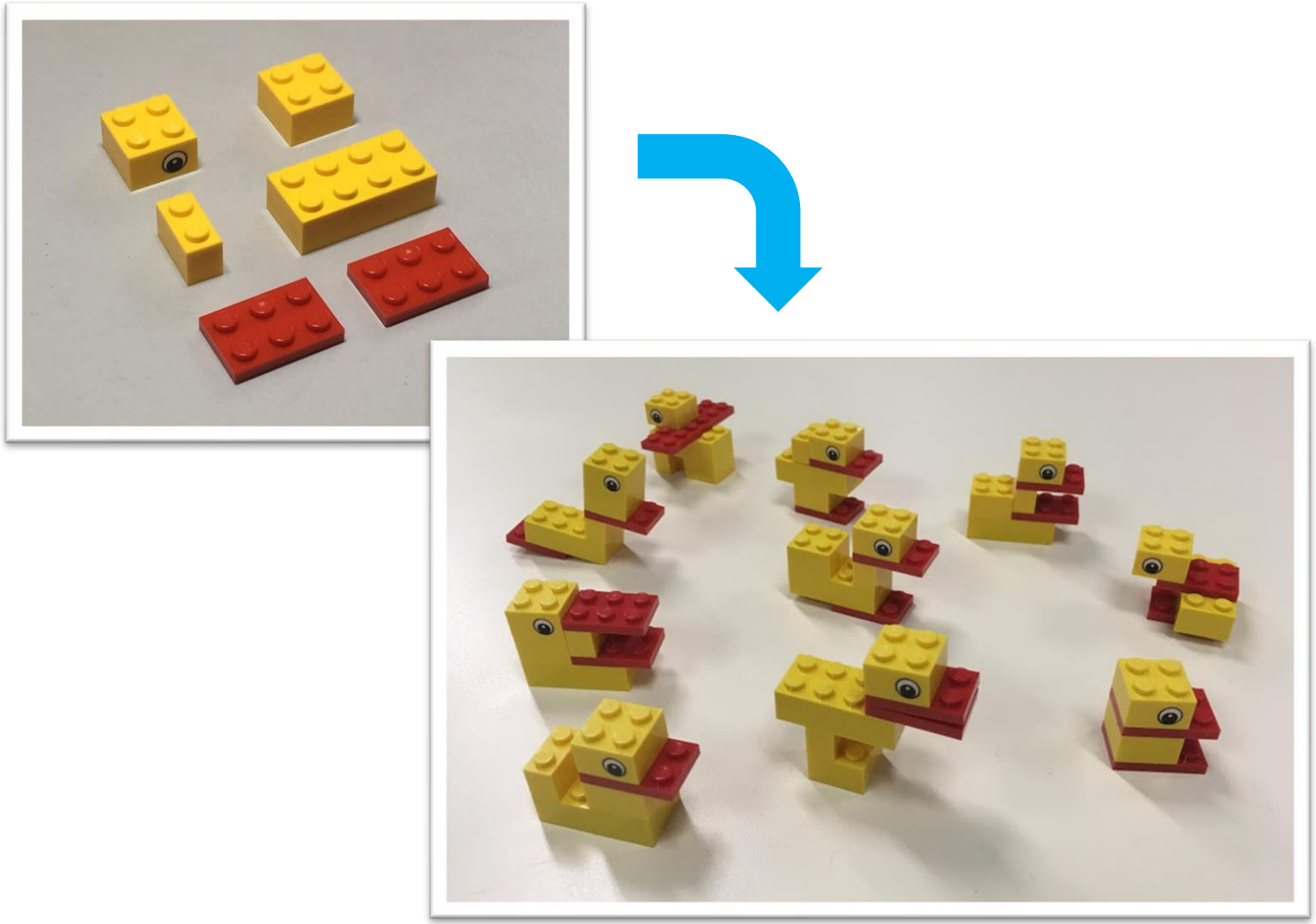
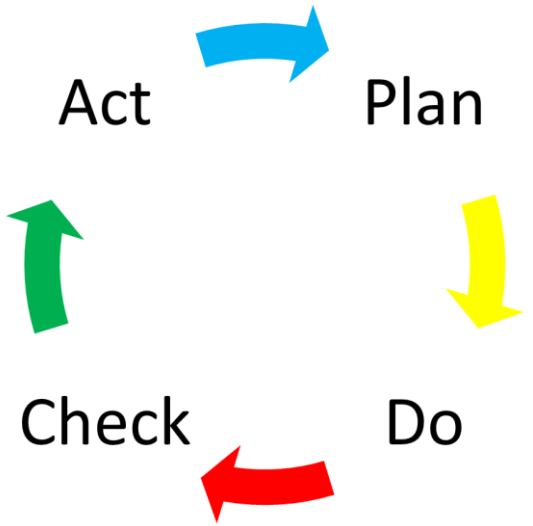
Change: be creative, be efficient, look ahead!





Source: http://www.legoengineering.com/build-a-duck/

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Some standards that can help

QMS-related:

- ISO 13485 + MDR - quality management

Product related:

- ISO 14971 - risk management
- IEC 62304 - software development
- IEC 82304-1 - standalone software
- IEC 62366-1 + IEC 60601-1-6 - usability
- IEC 60601-1 - electrical safety and EMC
- ISO 10993 series - biocompatibility
- MDCG 2020-13 + MDCG 2020-6 - clinical evaluation (formerly MEDDEV 2.7/1 rev. 4)

User information related:

- ISO 15223-1 - medical device symbols
- ISO 20417 - information to be supplied by the manufacturer
- Incorporated in several standards

Production process related:

- ISO 11135 / ISO 11137-1 - sterilization
- ISO 11607-1/2 - packaging

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