



Innovation and product
development
from today's perspective

madita. / maxi.

The Idea.



- Ideas come from the sales force, the management or customers
- Internal strategic meeting to prioritize ideas for new products or product updates
- Kick Off meeting for every new project with sales force, management and technical experts

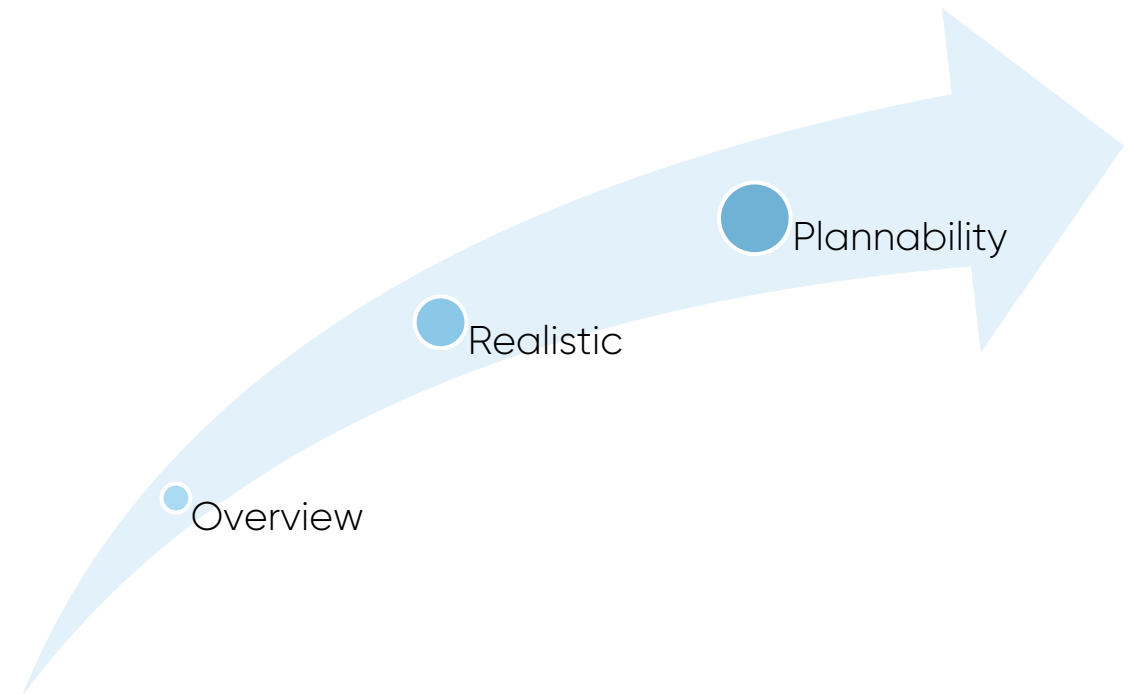
→ Outcome: List of requirements



Project planning.



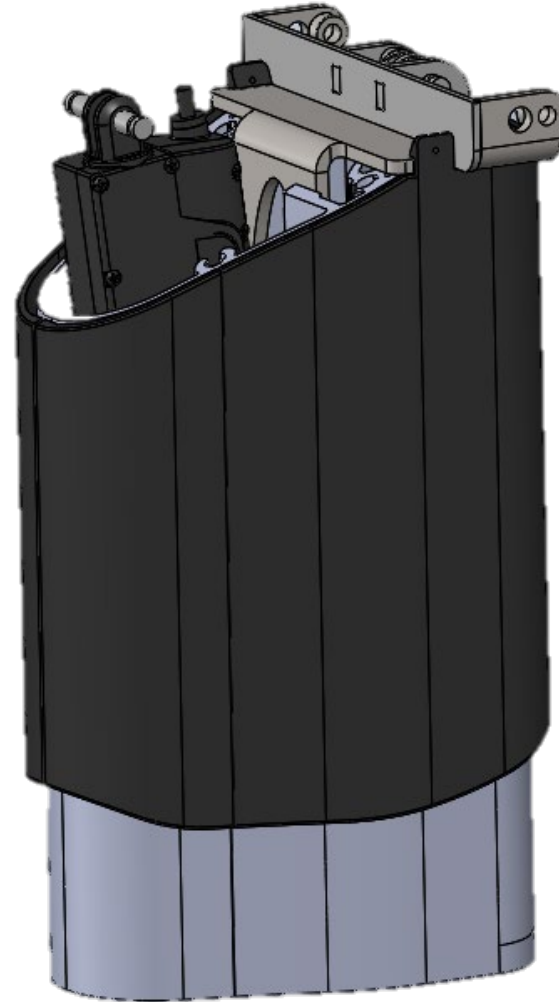
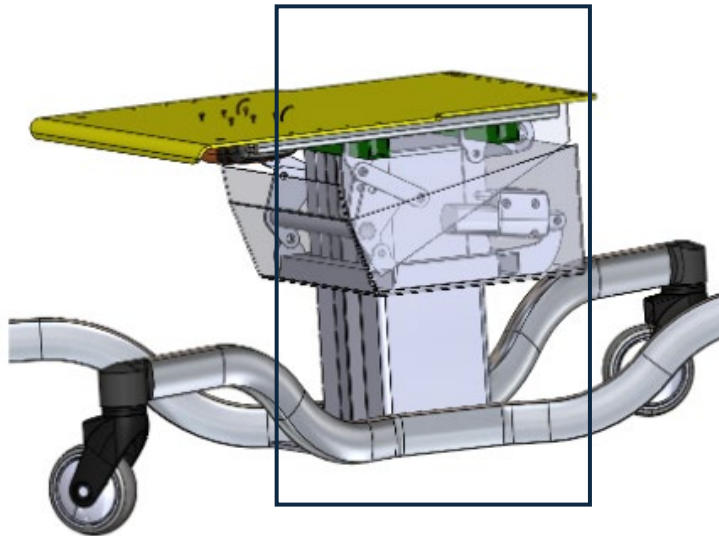
- Split the project into pieces
 - Phases, Tasks and sub Tasks
- assessment of the effort of the tasks
- Set responsibilities for the different tasks
- Find the right range for internal meetings
- Initial budget planning





Concept Phase.

- Find possible solutions
- Evaluate
- Select
- „Design“

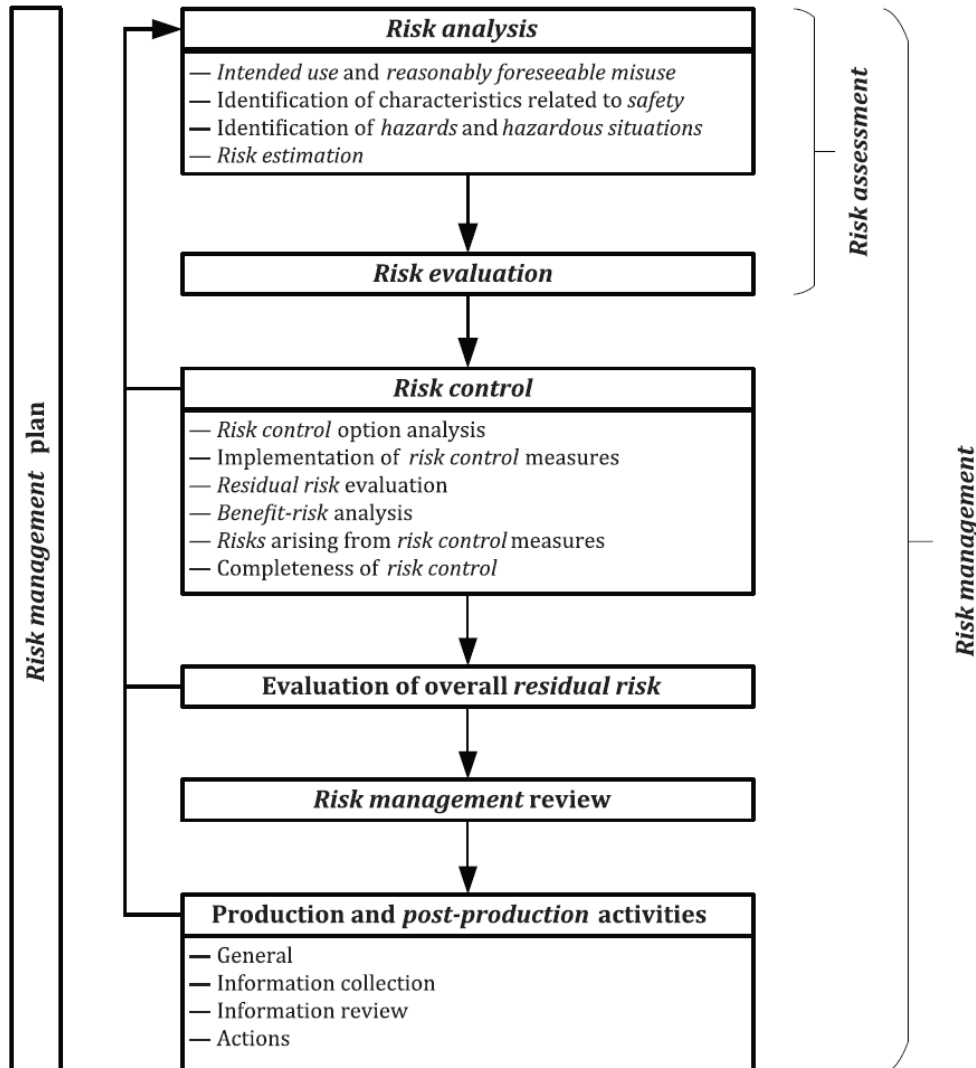


Prototypes.

- For Physical „feeling“ or function
- For testing and evaluation
- 3-D Print (Metall, plastic, rubber)
- CNC
- Welding



Risk Management.



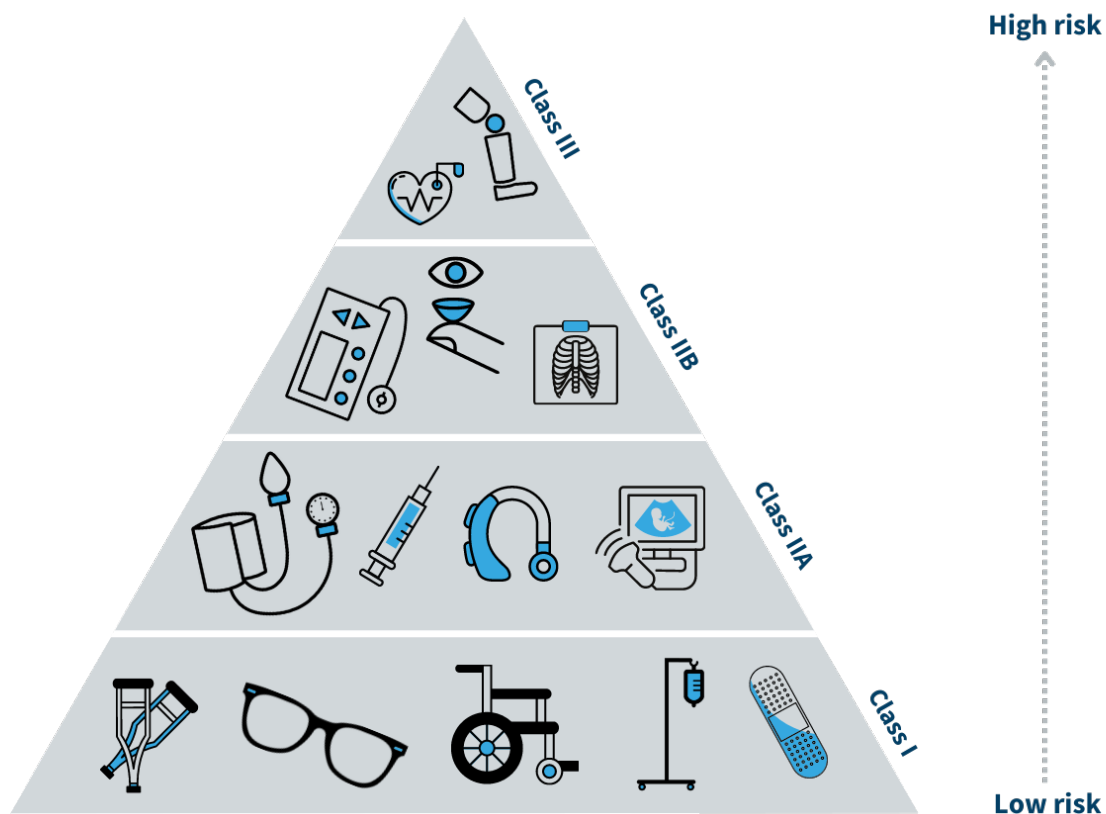
- According to ISO 14971
- Ensure that risks are known and acceptable
- Risk management is performed in all phases of the product life cycle

Benefit-Risk Analysis.



The overall residual risk is acceptable, when it is outweighed by the benefit of the device.

Benefit-Risk Analysis.



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Risk Matrix.



	Minor	Moderate	Major	Critical
Frequent	MEDIUM	HIGH	HIGH	HIGH
Probable	LOW	MEDIUM	HIGH	HIGH
Remote	LOW	LOW	MEDIUM	HIGH
Improbable	LOW	LOW	LOW	MEDIUM

Probability

Frequent: More than 1 in 400 products per year of use

Probable: Less than 1 in 400 products and more than or equal to 1 in 800 products per year of use

Remote: Less than 1 in 800 products and more than or equal to 1 in 8,000 products per year of use

Improbable: Less than 1 in 8,000 products per year of use

Severity

Minor: Inconvenience or temporary discomfort

Moderate: Results in temporary injury or impairment not requiring professional medical intervention

Major: Results in injury or impairment requiring professional medical intervention

Critical: Results in permanent impairment or life-threatening injury

Examples Risk Analysis Madita Maxi.



RISK	HAZARD	HAZARDOUS SITUATION	HARM	CAUSE	INITIAL RISK			MITIGATION ACTION	RESIDUAL RISK		
					SEVERITY	PROBABILITY	RISK		SEVERITY	PROBABILITY	RISK
 > 	Mechanical energy	Insufficient stability – Therapy chair tips over	Bruises, contusions, fractures	Design flaw	critical	remote		Product design based on ISO EN 21856; Application and safety instructions regarding tilt stability in the instructions for use;	critical	improbable	
 > 	Biocompatibility	Skin contact causes skin irritation	Skin irritations due to allergic reactions; urticaria, contact dermatitis	Incorrect choice of materials; contain allergens	moderate	remote		Exclusive use of harmless and established materials for parts with direct skin contact; evaluation of the materials used in accordance with DIN EN ISO 10993-1	moderate	improbable	
 > 	Product life cycle	Damage or malfunctions are not detected because the device has not been checked and repaired	Bruises, contusions, bruising of body parts; injuries caused by the user falling	Unclear description in IFU; missing warnings; lack of instructions for maintenance	major	remote		Clear information on use, maintenance and servicing in the IFU	major	improbable	

Examples Risk Analysis Madita Maxi.



	Minor		Moderate		Major		Critical	
Frequent	Initial	Residual	Initial	Residual	Initial	Residual	Initial	Residual
Probable	Initial	Residual	Initial	Residual	Initial	Residual	Initial	Residual
Remote	Initial	Residual	Initial	Residual	Initial	Residual	Initial	Residual
Improbable	Initial	Residual	Initial	Residual	Initial	Residual	Initial	Residual

Initial:

- 23 low risks
- 26 medium risks
- 5 high risks

Residual:

- 49 low risks
- 5 medium risks
- 0 high risks

The overall residual risk is outweighed by the benefit of the device
→ ACCEPTABLE

Product testing.



Prüfbericht Nr.: PB - 13 - 186 - MP - PA 137 - N2
 Technische Hilfen für behinderte Menschen
 Seite 1/29, 2015-07-10

BERLIN CERT

Prüfstelle: Berlin Cert - Prüf- und Zertifizierungsstelle für Medizinprodukte GmbH
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Auftraggeber: BEO MedConsulting Berlin GmbH, Helmholtzstraße 2, A5.0G, D-10587 Berlin

Hersteller: Schuchmann GmbH & Co. KG, Döllestraße 3, D-49205 Hasbergen

Prüfmuster: Typ / Modell: Therapiestuhl / MADITA-Fun
 Anzahl / Identifikation: 1 / SN 2154380515-0151351
 Eingang / Zustand: 2013-07-30 / Vorführmodell

Prüfstandard: DIN EN 12182:2012 Technische Hilfen für behinderte Menschen – Allgemeine Anforderungen und Prüfverfahren

Anmerkung: Die Nummerierung des Prüfberichtes entspricht der angewandten Norm DIN EN 12182:2012

Akkreditierung: Akkreditiert durch die Deutsche Akkreditierungsstelle GmbH (DAKKS) (Reg.Nr.: D-PL-17591-01-01)

An der Prüfung: Kompletprüfung

Prüfzeitraum: 2013-07-30 bis 2013-10-15; 2015-07-01 bis 2015-07-10

Prüfart: Räume der Prüfstelle

Prüfresultat: Die Prüfanforderungen sind erfüllt.

erstellt: 2015-07-10 freigegeben: 2015-07-10

M. Fiedler *A. Abmann*
 Dipl.-Ing. (FH) M. Fiedler Dipl.-Ing. (FH) F. Abmann
 Technischer Leiter Produkt

Dieser Prüfbericht darf nicht ohne schriftliche Genehmigung der Berlin Cert GmbH ausgetauscht, veröffentlicht oder weitergegeben werden. Die Ergebnisse stellen nicht ausschließlich auf das hier angegebene Prüfobjekt und dessen allgemeine Eigenschaften und die Eigenschaften der nach der Prüfung vor.

PS-001-X00-MP-PA 137 Rev. 0.1, 2013-06-20

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 Deutsche
 Akkreditierungsstelle
 D-PL 17591-01-01

Product testing.

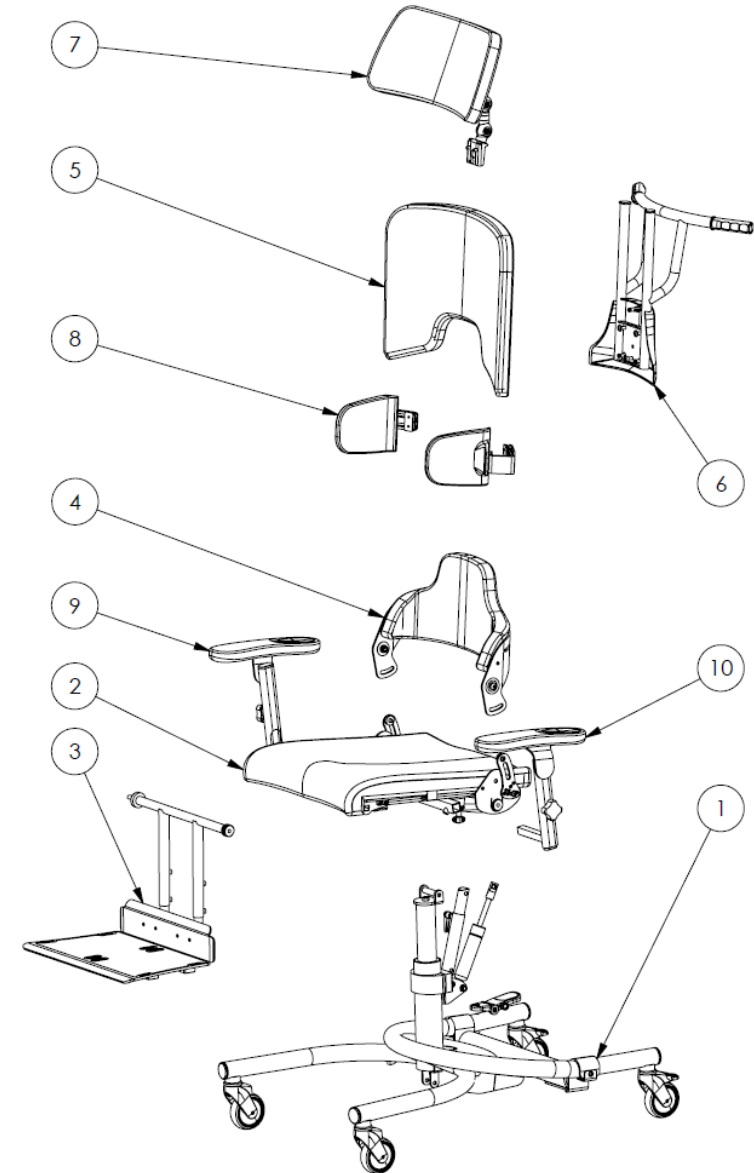


freddy.



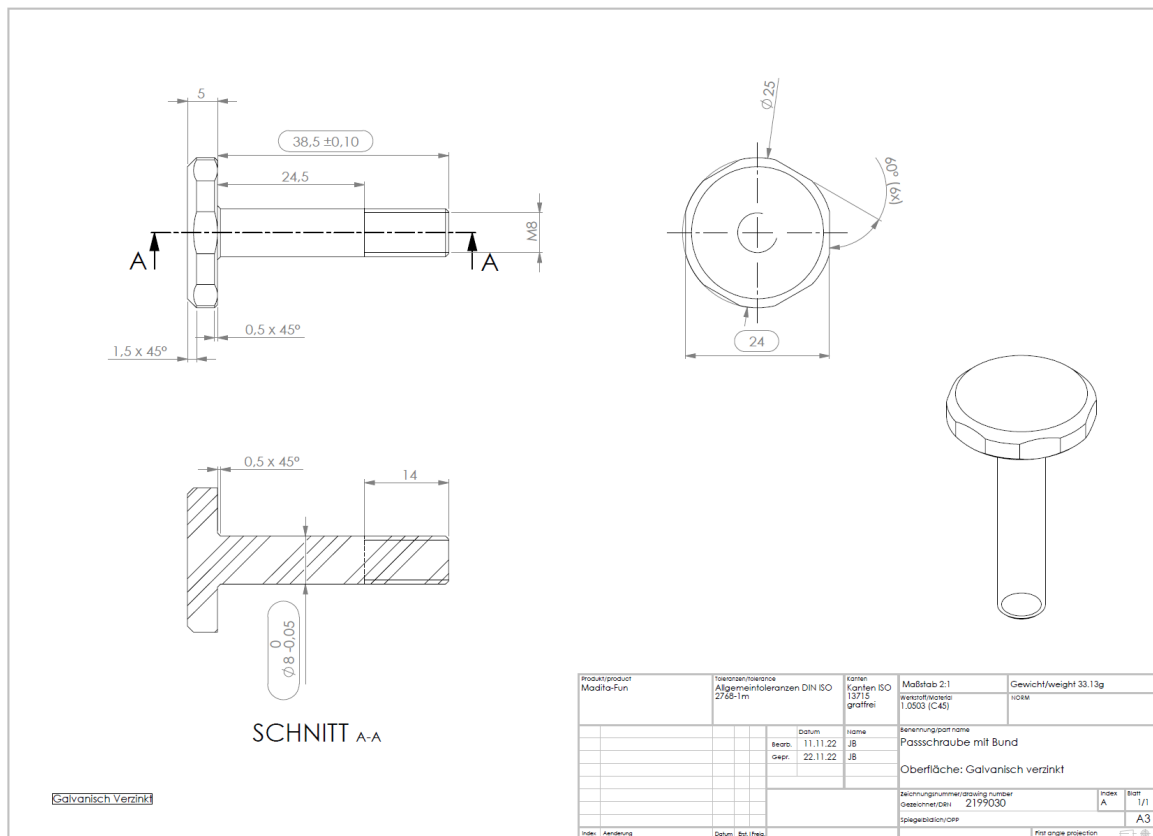
Realisation phase.

- Finalize drawings for purchasing parts
- Finalize BOM's (bills of material)
- Tool manufacturing for plastic parts
- User Manual and price list
- Configurator
- Product testing
- Certification



Realisation phase.

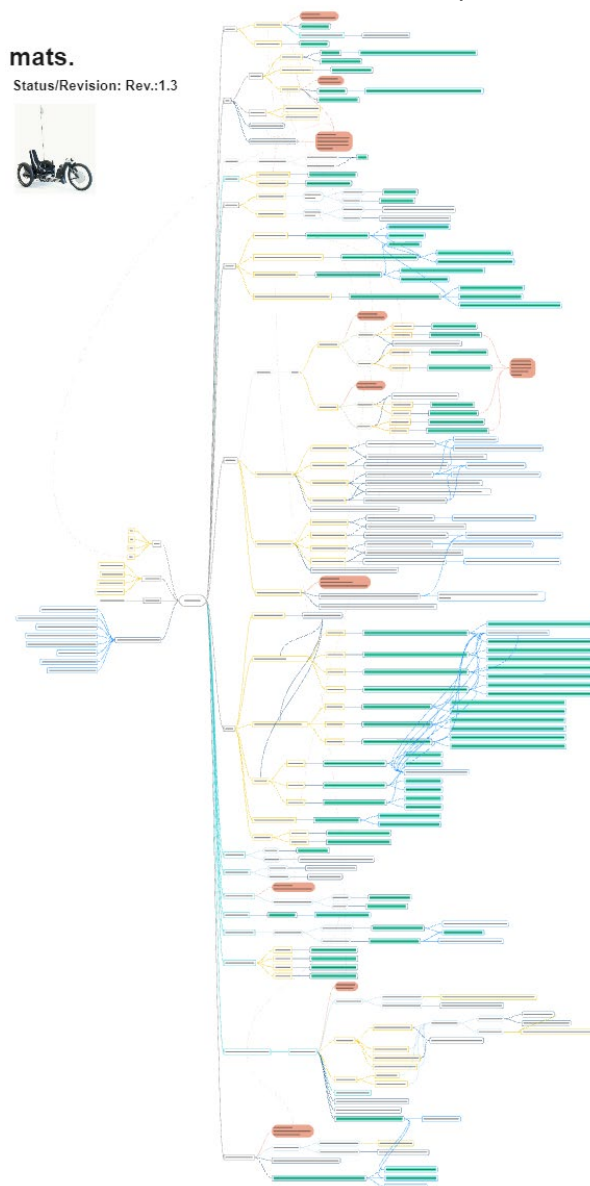
Fitting Screw **mädita-fun.**



Miro Board structure plan

mats.

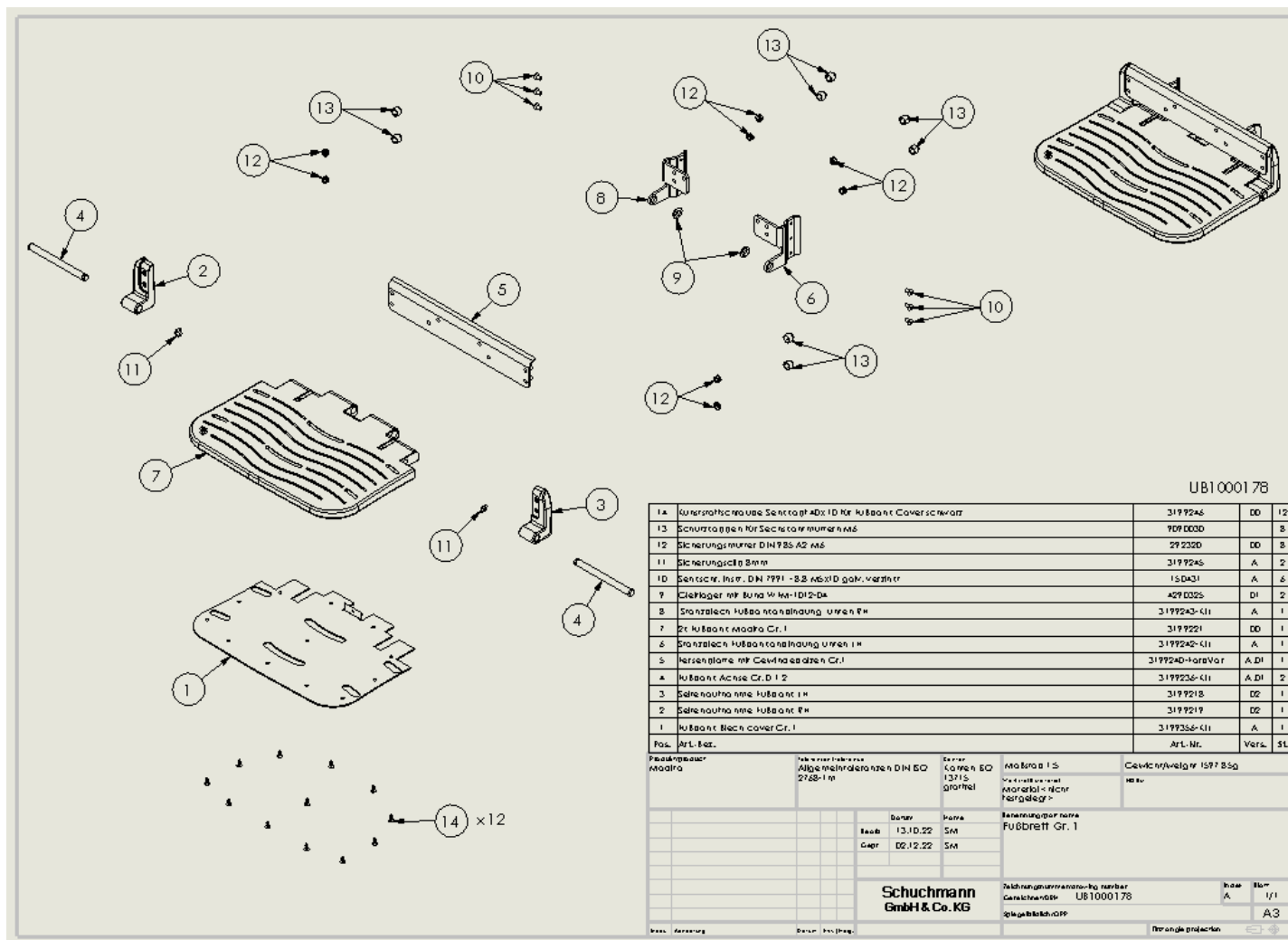
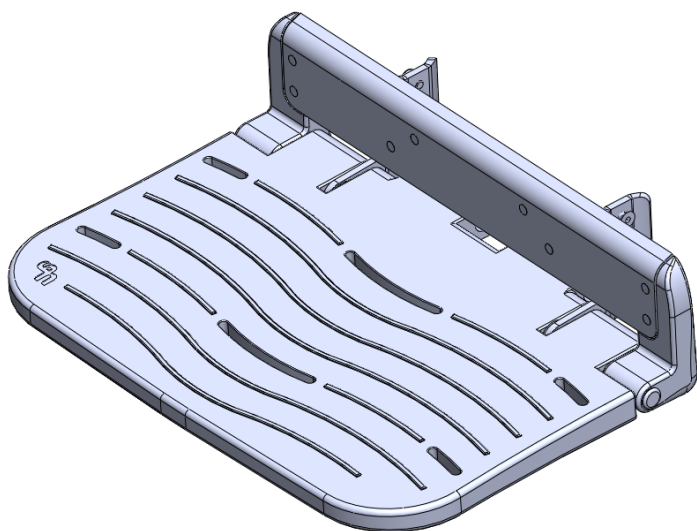
Status/Revision: Rev.:1.3



Series production.



- Parts to be ordered
- Drawings
- Assembly lines
- 0 – Series
- Quality Management
- Start Production





**Thank you for
your attention!**