

Reprocessing of Single-use Medical Devices

MDR art. 17, chapter 3 - from a Danish Perspective



OUR WORLD
OUR RESPONSIBILITY

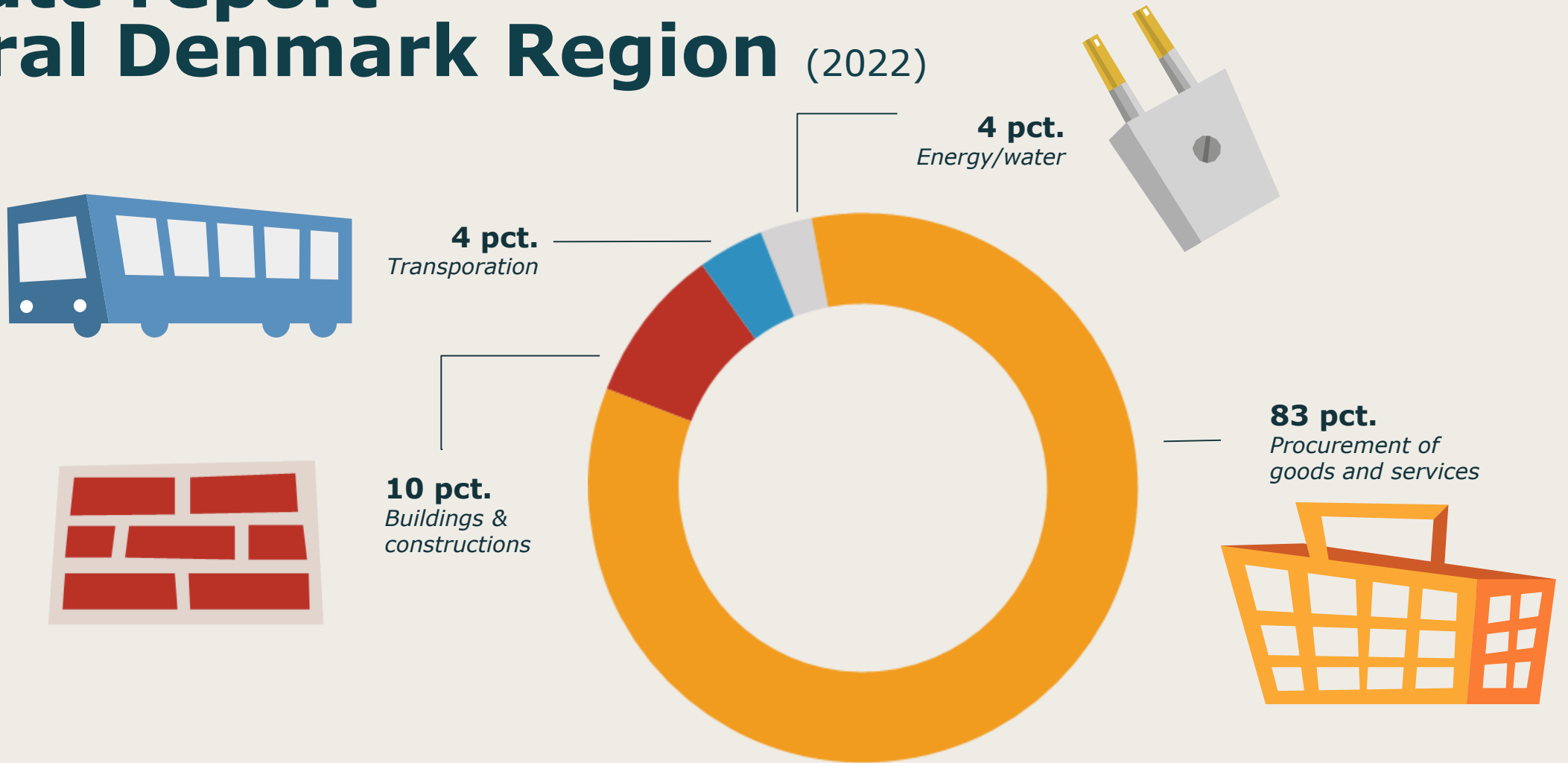
Center for Sustainable Hospitals

According to WHO
climatechange is the largest threat against
people's health in the 21st century**

Healthcare – should we care?

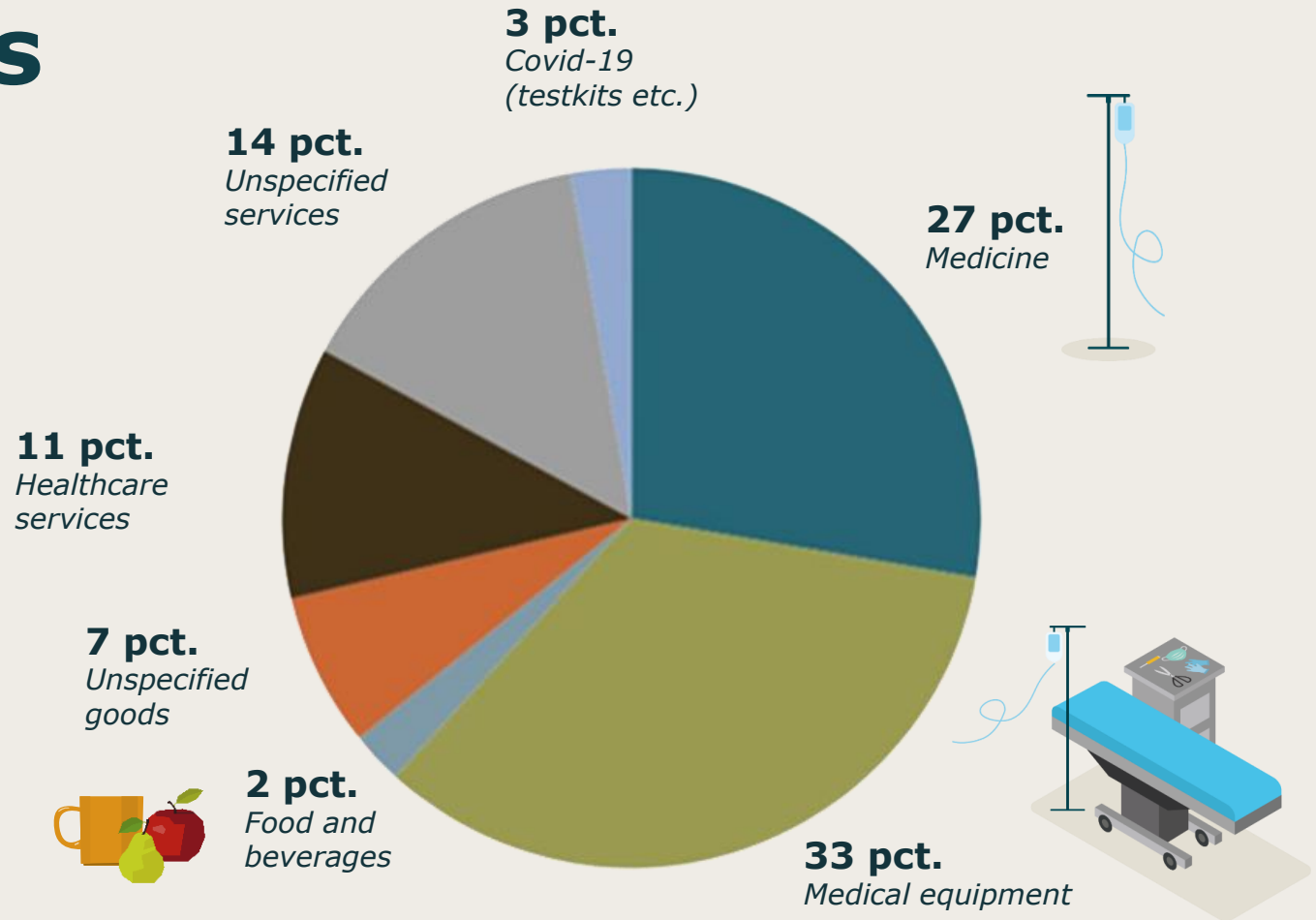


Climate report Central Denmark Region (2022)



Procurement of goods and services

CO2-emissions in categories (2022)



Kilde

Strategy for sustainability 2030



Circular Economy



Electricity, Water
& Heating



Logistics, Transport
& Mobility

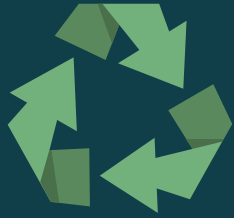


Social Responsibility

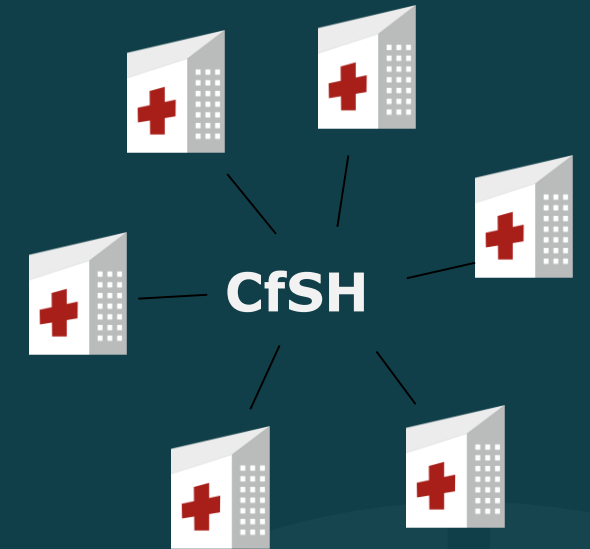


- 70 % CO2-reduction
- 30 % reduction of consumption in scope 3 (Dkr)
- 30 % reduction of waste (tons)
- 70 % recycling (23% in 2021)





Center for Sustainable Hospitals



PURPOSE

*To support all units in **reaching the strategic CE-goals**, by **mobilizing the employees**, creating transition through **knowledge and action**, and to strengthen **national and international cooperations, research and political awareness**.*

Why would we want to reprocess single-use medical devices?

- Sustainability
- Security of supply
- Cost saving?



Why would we be in doubt, if we should reprocess single-use medical devices?

- Patient Safety
- Lack of clear evidence in regard to hygiene
- Work enviromental issues



What is our top priority?

- Prevention
- Multiple-use medical devices
(*when safe*)

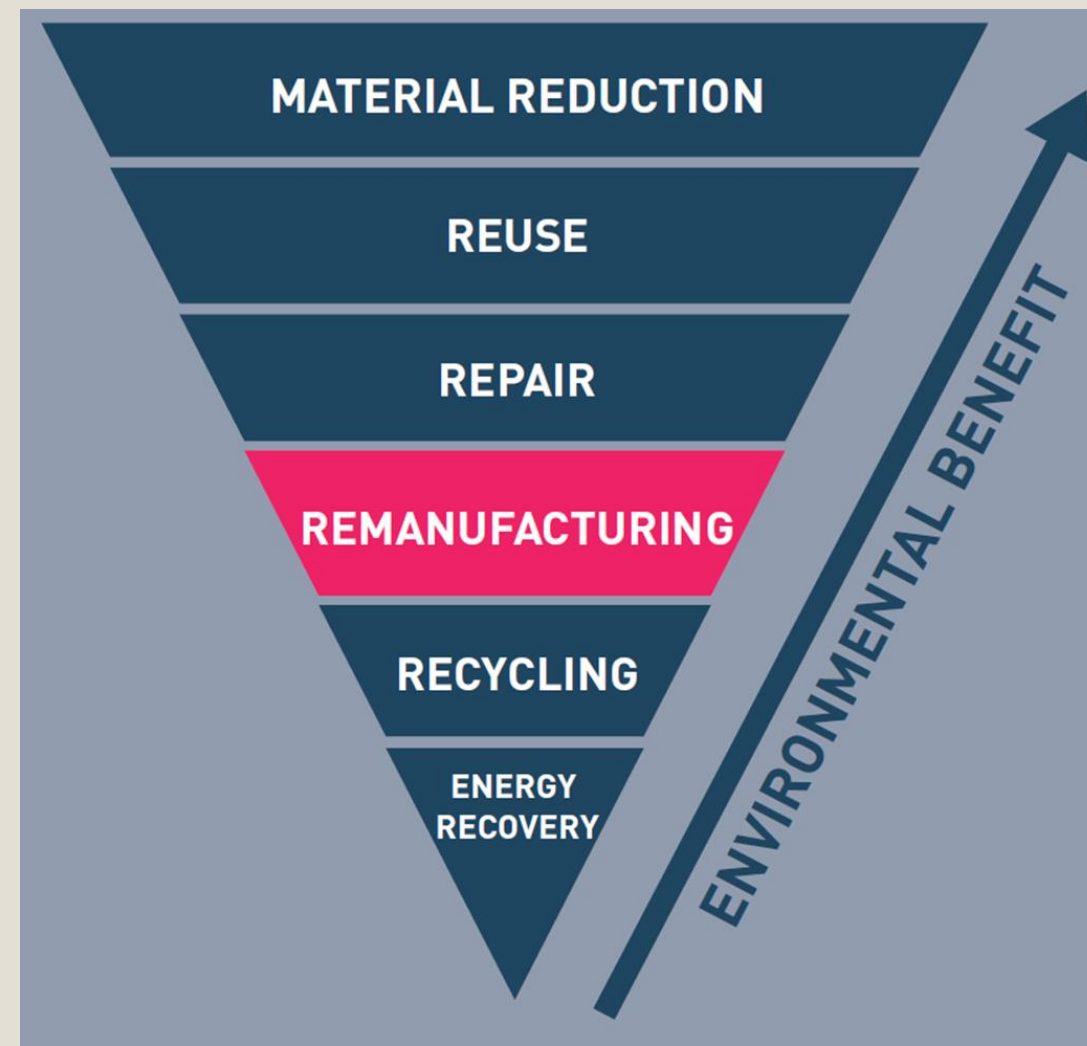
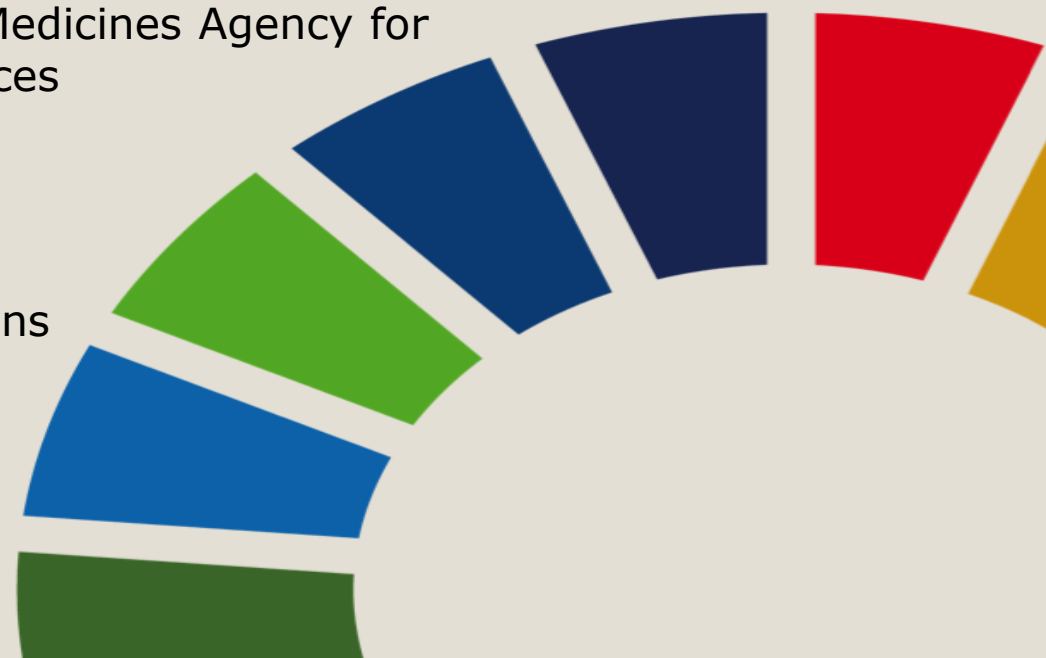


Figure 2. The possibilities for health care facilities to improve their environmental footprint. The figure is created with inspiration from Vanguard AG and the EU waste hierarchy.

What happened in Denmark?

- Before the new EU's Medical Device Regulation (MDR) became effective on the 26th of May 2021, the heart department at AUH had its catheters reprocessed by an external reprocessor in Germany.
 - We wanted to find out, if it made sense to apply the Danish Medicines Agency for national allowance of reprocessing of single-use medical devices
 - based on a tripple line businesscase analyses
- Working group established in Q1 2022 on behalf of all 5 regions
- National following group established



Stakeholders/partners involved

- | | |
|---|---|
| <ul style="list-style-type: none"> • Danske Regioner • Lægemiddelstyrelsen • Statens Serum Institut • Dansk Selskab for Klinisk Mikrobiologi • Fagligt selskab for Hygiejnesygeplejersker • Dansk selskab for Centralsterilisering og Sygehushygiejne • Lægeforeningen • Dansk selskab for Patientsikkerhed | <ul style="list-style-type: none"> • Region Syddanmark (Klinisk mikrobiologisk afd. og Projektorganisation for byggeri og grøn omstilling) • Region Nordjylland (Regional Udvikling) • Region Hovedstaden (Center for Økonomi, Klinisk mikrobiologisk afdeling, Hvidovre Hospital og Den Regionale Sterilcentral) • Region Sjælland (Regional Udvikling) • Region Midtjylland (Klinisk Mikrobiologisk afdeling og Sterilafdelingen, AUH) |
|---|---|

Status og experiences from other Western countries

Legal	Ulovligt	I proces
USA	France*	Spain
UK	Finland*	Portugal
Germany*	Slovakia	Italy
The Netherlands	Cypres	Slovenia
Sweden*	Estland	Denmark
Croatia	Greece	Norway
Belgium*	Schwizerland	
Ireland	Latvia	
	Lithuania	
	Malta	
	Rumania	
	The Czech republic	
	Austria	

Kilder: Listen er sammenfattet baseret på arbejdsgruppens kortlægning i foråret 2022, [EU's hjemmeside for MDR art. 17](#) samt AMDR's kortlægning. * markerer de lande arbejdsgruppen har været i dialog med. For link til Norges status, se [her](#).

Arguments/ points of discussion

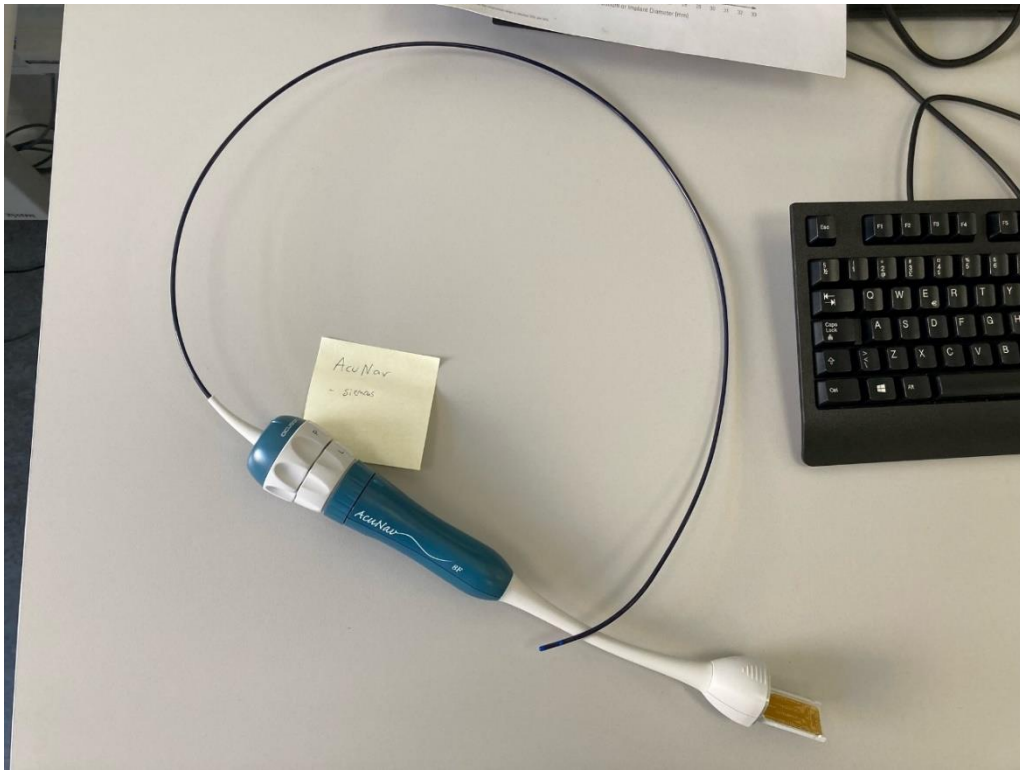
Pro

- Data shows no causality between reprocessing and infections
- Cost saving
- Security of supply
- Lower impact on climate and environment
- Lower consumption of raw materials

Cons

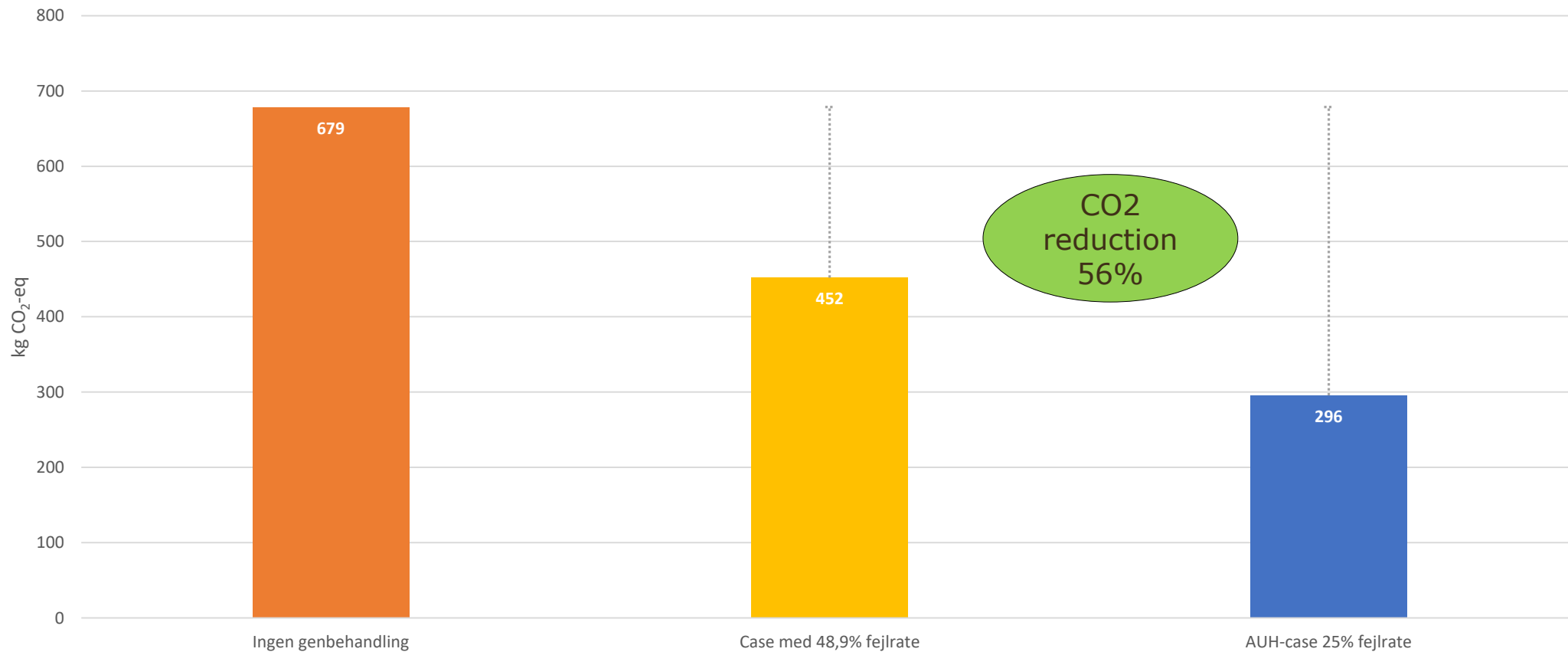
- Lack of Evidence
- Is it cost saving?
- Is it more climate/enviromental "friendly"?

Case from Aarhus University Hospital



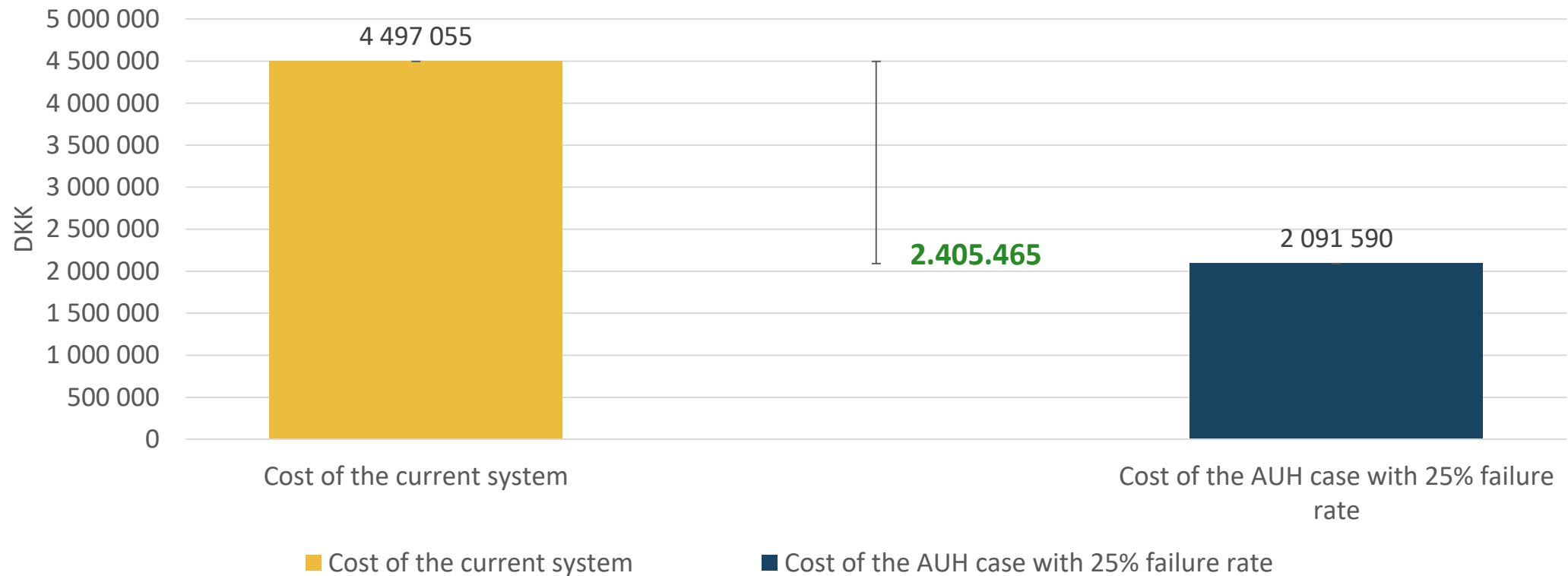
(As far as we know, this product is not available on the market in a multiple-use version)

CO2 emissions (LCA)



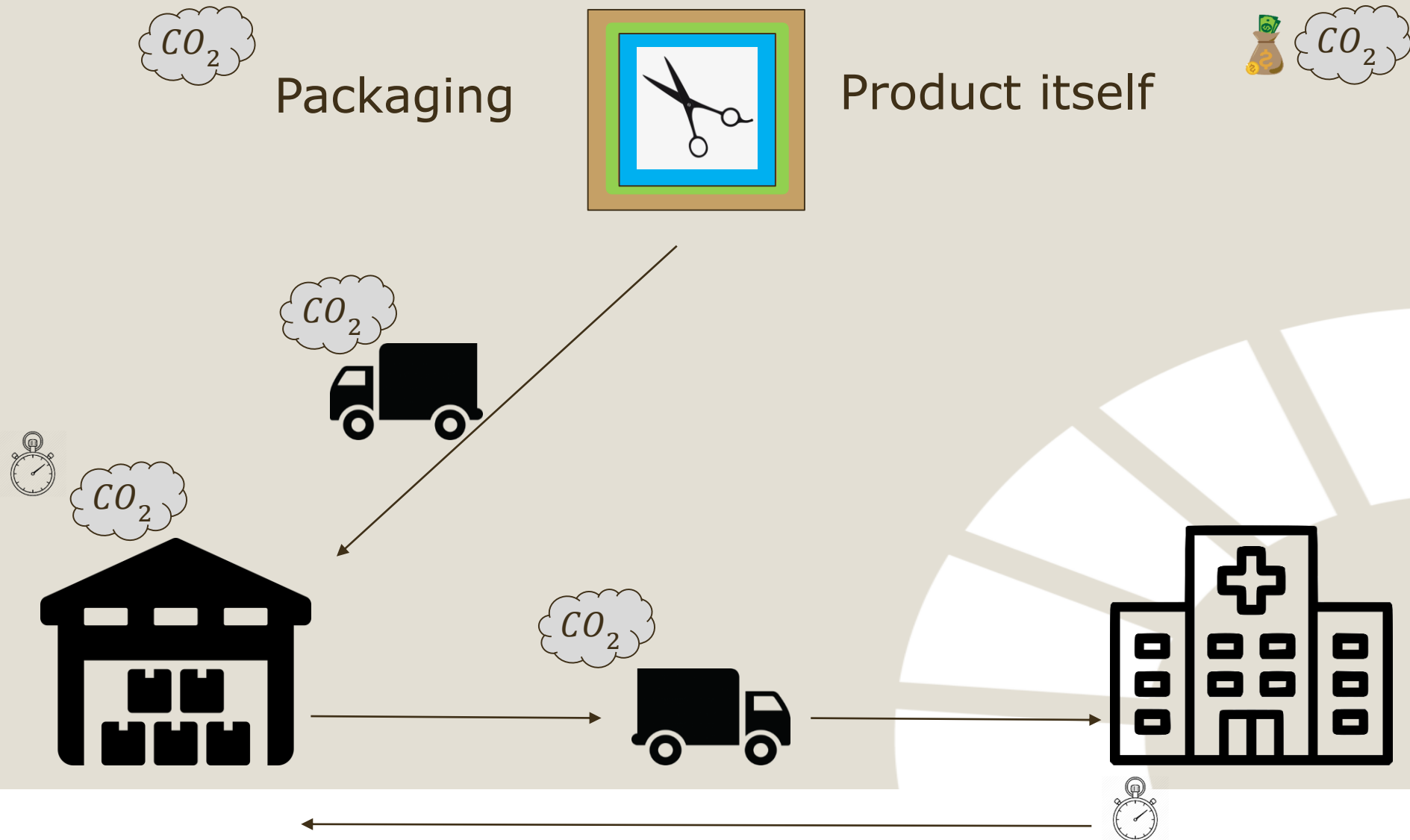
Total Cost of Ownership, pr. year

Price difference for one year with a 25% failure rate

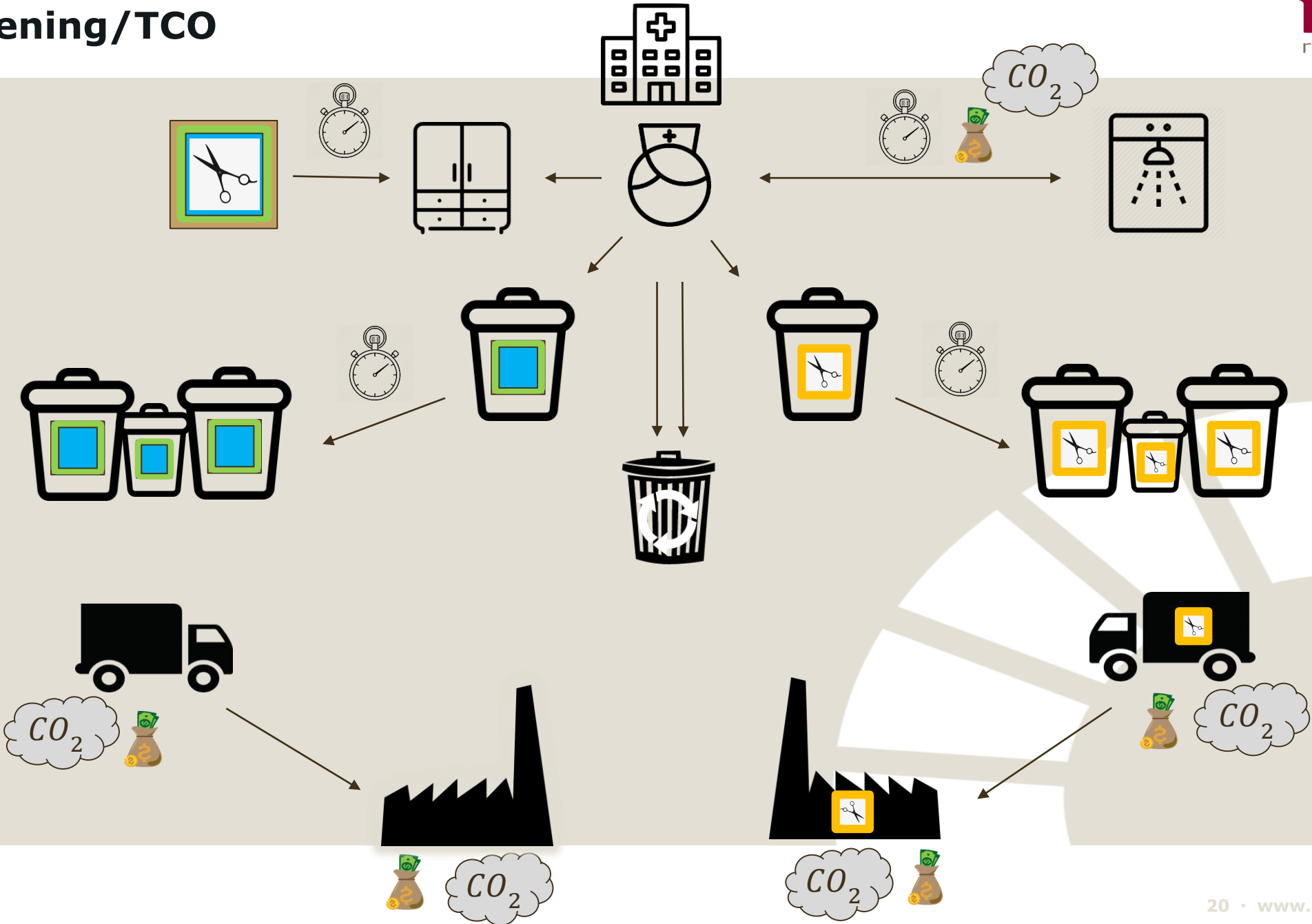


What is included in the analyses?





LCA screening/TCO



What is not included?



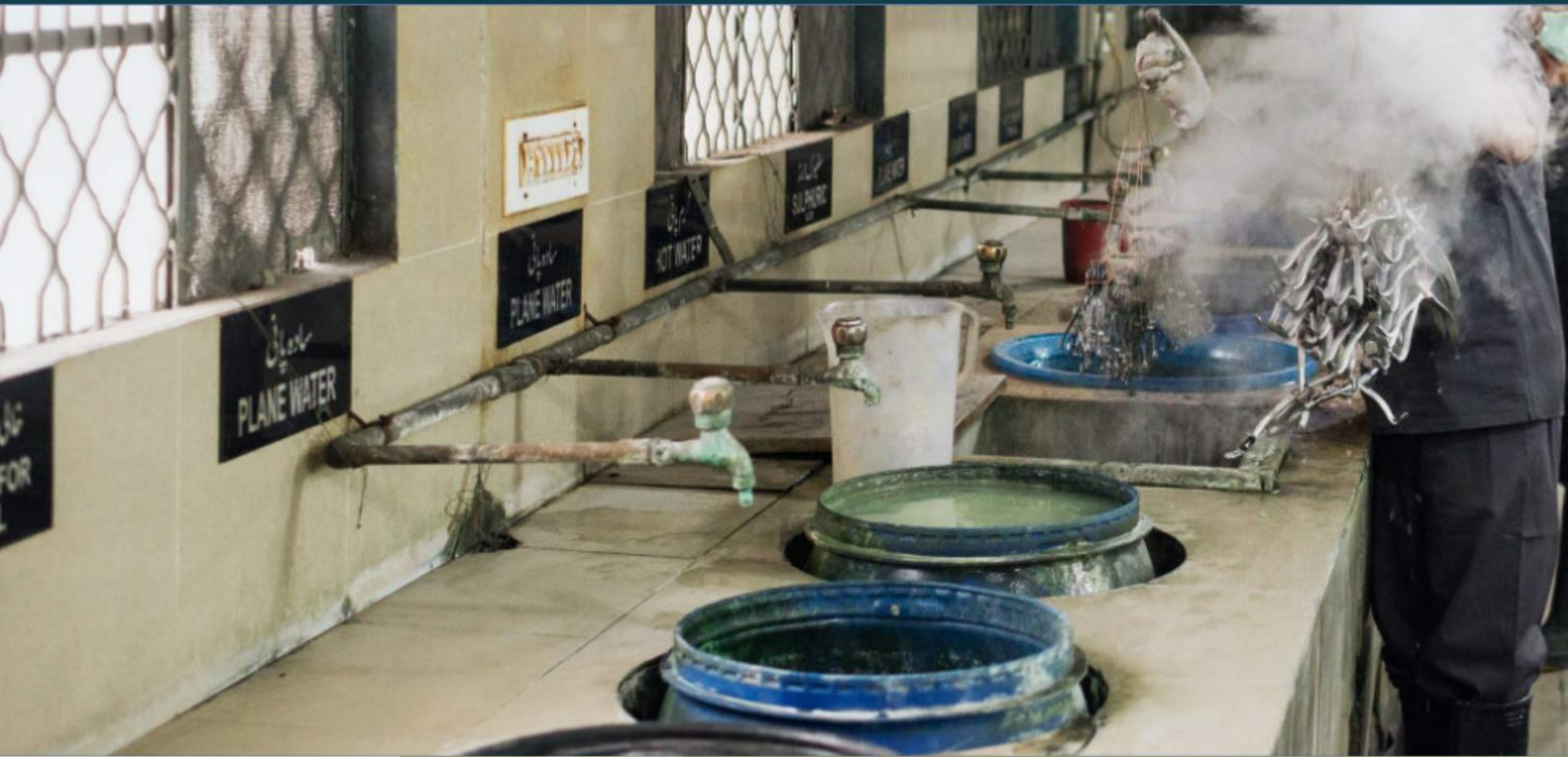
Social/Ethical Sustainability



Kilde: BMA [Is this ethical trade? \(bma.org.uk\)](http://bma.org.uk)



Children at work in an unregulated workshop making surgical tools



What is Safe and Sustainable?

- **Security of Supply, what is it worth?**

- **Indirect effects of climate change?**

(threat to health broadly, intensifying the pressure on health systems, security of supply, global stability)

- **Raw materials – limited resources (→ price development?)**



What did it end up with?

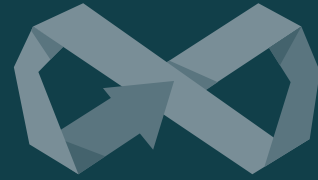
- *Current status in Denmark*

Research and analyses concluded

- Reprocessing has a number of advantages in regard to security of supply and would increase the national organisational healthcare resilience in case of future crisis.
- Reprocessing is advantageous in regard to both climate, environment and often also economics.
- That allowance should be given, while practical conditions for implementation should be planned in regard to the recommendations from "Statens Serum Institut", Ministry of Health

Application from all 5 regions made in January 2023:

"...Regionernes sundhedsdirektører havde primo januar 2023 en drøftelse af rapporten bag konklusionerne. Kredsen bakkede rapport og konklusioner op. Kredsen anmoder derfor om, at Lægemiddelstyrelsen tager skridt til at fastsætte nationale regler, der tillader genbehandling af højt specialiseret medicinsk engangsudstyr hos eksterne serviceudbydere i Danmark og andre EU-lande i overensstemmelse med MDR art. 17."



VORES VERDEN
VORES ANSVAR

Tak for opmærksomheden

www.voresbaeredygtighed.rm.dk
www.cfbh.rm.dk

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