

Promens

shaping plastics beyond the obvious



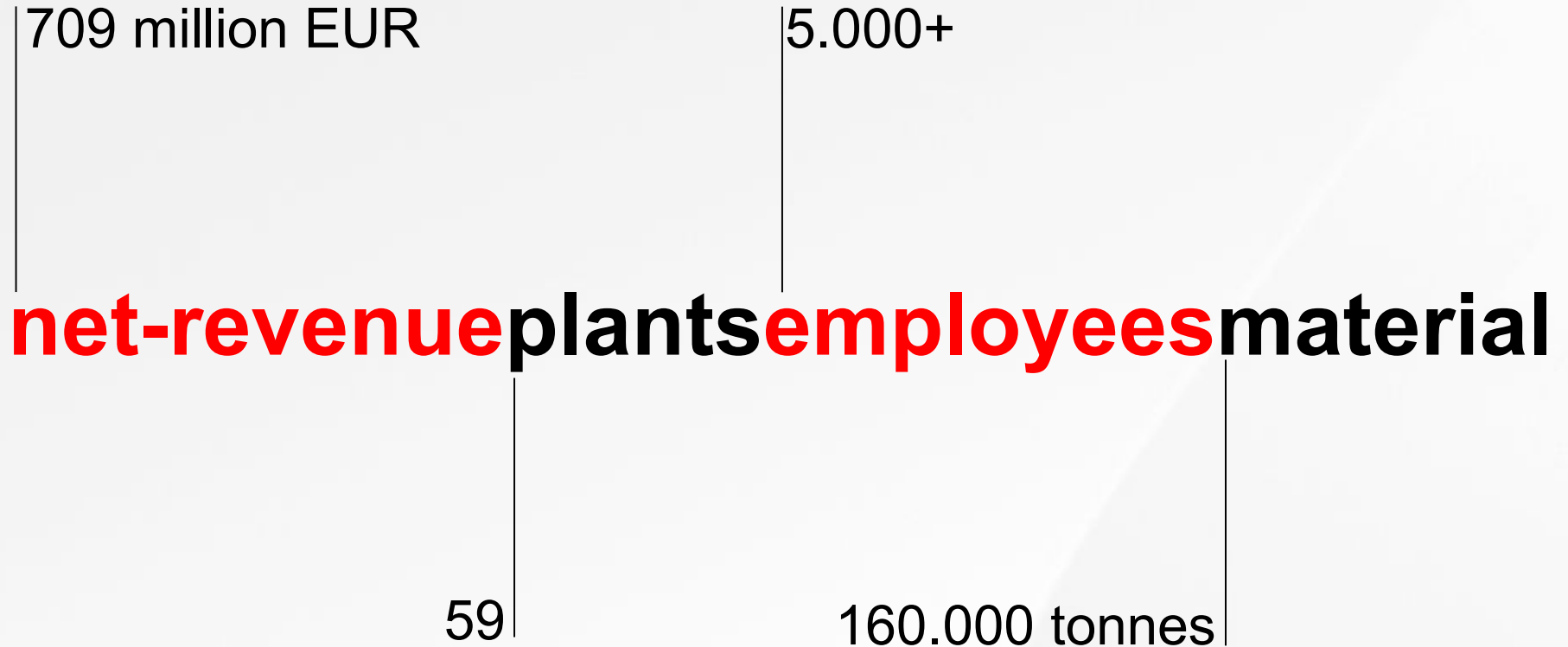

PROMENS

Strategic foundation and future focus



We shall master **operational excellence**
and create differentiation through
innovation

Key facts about Promens 2008



59 plants in 20 countries



Key business segments

COMPONENTS

137 M €



PACKAGING

450 M €



ROTOMOULDED

150 M €



5 core segments

Promens Packaging
450 M€

Chemical

100 M€

Food
& Beverage

150 M€

Medical

50 M€

Household

50 M€

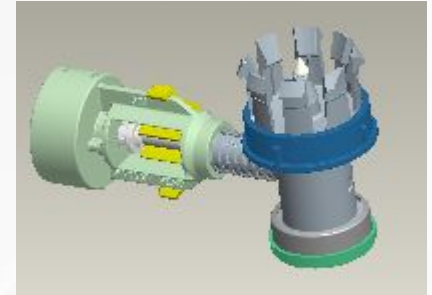
Personal care

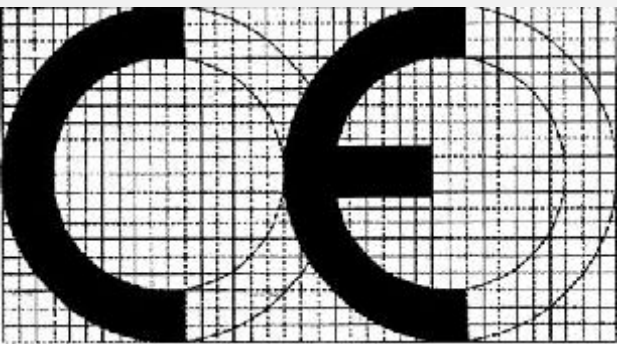
100 M€



Promens Medical Packaging A/S

- Markets
 - Pharmaceutical producers
 - Hospital Pharmacies
- Products
 - IV containers
 - Vials
- Employees : 110
- 5 shifts – 7 days/week – 24 h
- Technologies :
 - Extrusion Blow Moulding
 - Injection Blow Moulding
- Machines : 28
- Clean Room : Class 10 000 (C)
- High quality standards





Quality standards

ISO 9001

ISO 13485

GMP



Documents registration

Medical Device Manual

DMF registration,
(U.S. Drug Master File)

Eur.Pharmacopoeia

Specific registrations :

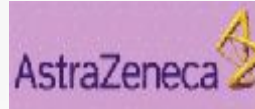
- USP test (U.S.Pharmacopoeia)
- Bacteriological test
- Particle test



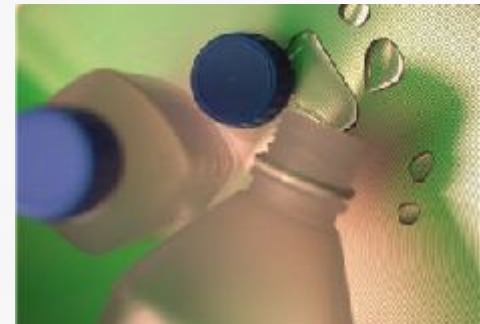
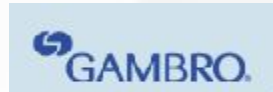
Medical



Bayer

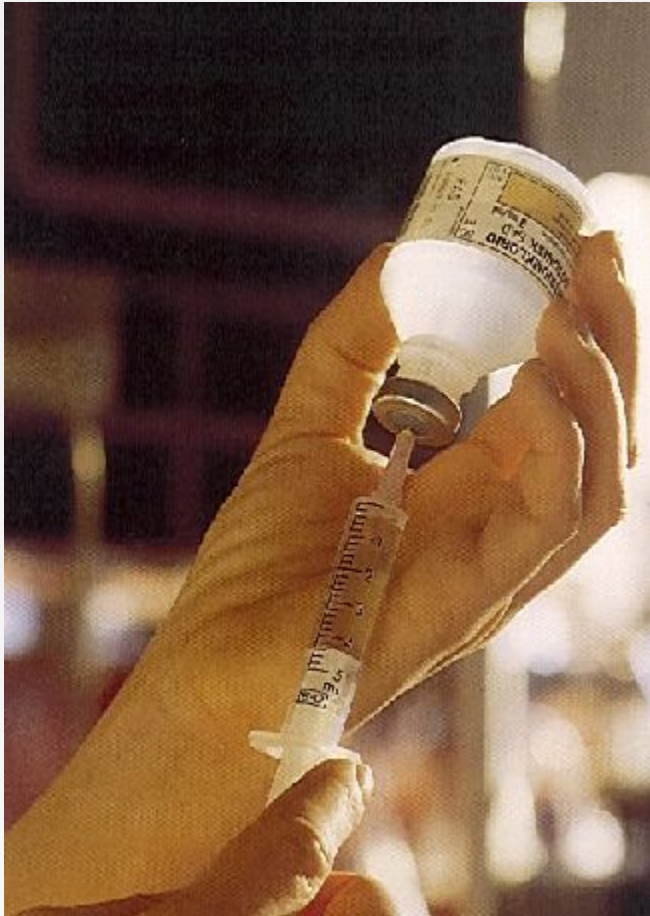


GE Healthcare




PROMENS

Products



Vials in material:
Polyethylene
Polypropylene



Products

Vials in material:

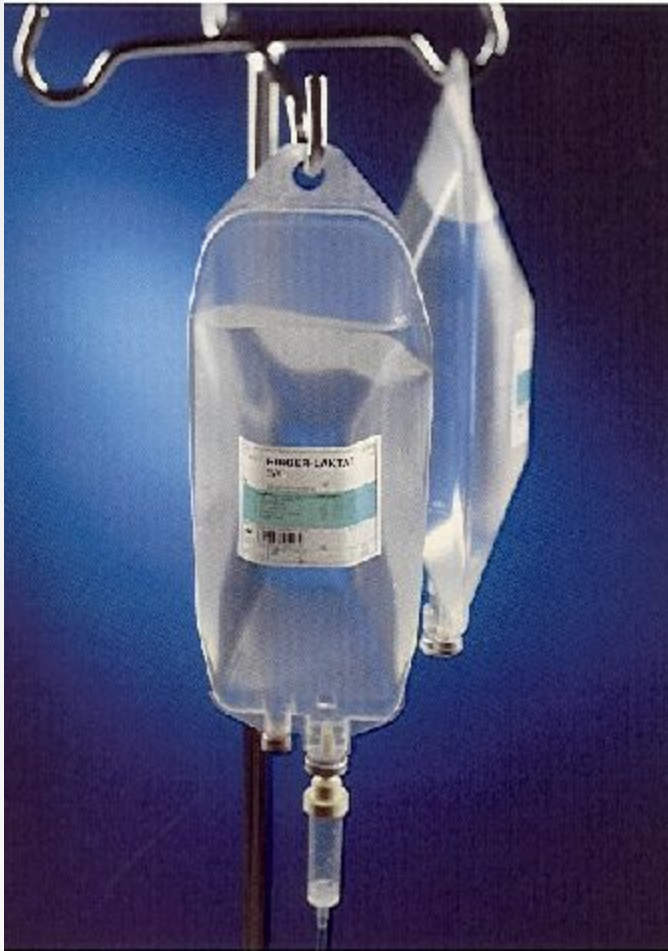
COC / COC – Amber (Cyclic Olefin Copolymer)

COP / COP – Amber (Cyclo Olefin Polymer)



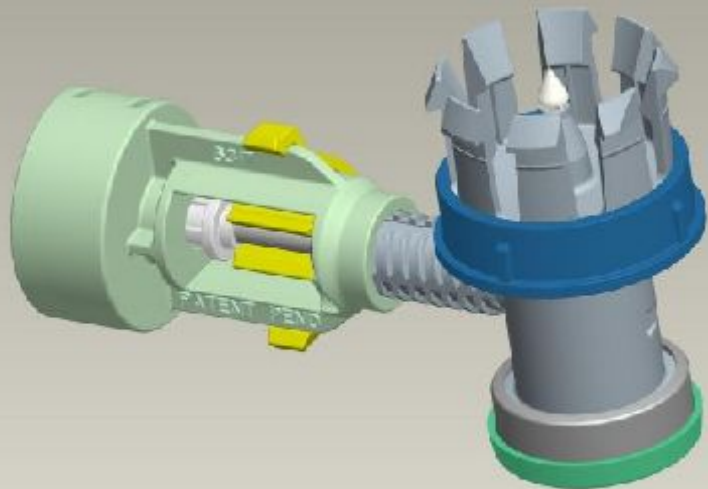
Products

IV Container





DivibaX



Mixing concept



PROMENS

Other products

- Clysma / enema bottles
- Blood plasma bottles
- Veterinary bags

Track Record & Customer References

- Promens Medical Packaging has established a customer base of more than 50 companies within the pharmaceutical and medical industry.
- We are proud to supply unique packaging solutions to global leading pharmaceutical companies like;



GE Healthcare



DivibaX[®]





Target

- Reduce workload for Healthcare Professionals
- Be better than existing systems
- Must avoid mistakes
- 100% closed system
- Mixing without contact with the active drug
- Easy to handle
- Improve the working environment
- Competitive on quality, price and delivery availability

Advantages

- Easy handling – does not take much power to fit neither IV-container nor vials
- Ready for immediate use
- Possible to assemble beforehand. The vial stays on so there is not doubt about the content of the IV liquid
- No contact to the active ingredient before mixing
- Possible to mix beforehand by members of the staff with more time, the person going to use / give the IV liquid can be absolutely sure that the content is correct

Advantages

- Can be assembled automatically, semi-automatically or manually.
- When the system is connected and the yellow safety-lock is still in place the system has a long shelf-life. We estimate min. 6 months – as there is only penetrated to the IV-container and not the vial, this means that there is not tampered with the active ingredient.

Focus on Safety

- Closed system – advantage for the **work environment and staff**
- No disassembling – advantage for the **work environment and staff**
- No needlesticks – advantage for the **staff**
- Ensures traceability – the vial stays on, meaning **patient safety**, sure of getting the right treatment
- No double medication – **patient safety**
- Eliminates run-back of fluid – **patient safety**
- No contamination – a closed and sterile system – **patient safety**

Use

In Denmark we aim at using the DivibaX for:

- 1) antibiotics for adults and
- 2) cytostatics.

It has to be in regular or fixed doses as the total content of the vial will be transferred to the infusion liquid.

Documentation

- CE class 1s
(sterile class 1 device - 93/42/EEC).
Approved by notified body (DGM).
- Medical Device Manual
- Promens quality system
- FDA – 510(k) for the U.S. market is ongoing



Thank you
for your
attention


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Promens wish you all a nice day

