

*No. 1 choice
of hospitals
& mothers*

Disposable products for hospitals

for human milk pumping, collection, storage, handling and feeding

The expanding volume of hospital procedures, coupled with the upgrading and enforcement of infection prevention standards, are putting pressure on hospital processes. Safety has to be ensured by preventing infection and promoting improved health – and this should be done in a cost-effective manner.

Disposable consumables were developed specifically to provide a hygienic solution, eliminating disinfection or sterilisation processes in the hospital. Moreover, Medela understands that each hospital's situation is unique and has expanded its range of disposable products to support each customer in the way that is needed.

A solution for every hospital and every situation

Medela now offers a complete and comprehensive range of disposable products that are available as both Ready-to-Use and sterile versions. They are intended for single or one-day use in hospitals, without a need for cleaning prior to first use – which saves time and costs. This integral product solution perfectly fits individual hospital situation and ensures the best support for mother and infant.

Ready-to-Use



- ✓ Products formed at over 150 °C – destroying potential pathogens
- ✓ Production and packaging take place in a clean room under laminar flow*
- ✓ Samples from every LOT microbiologically tested¹ before release
- ✓ More than 10 times cleaner than bottled water²
- ✓ Hygienically safe³ and cost-effective choice to use for term infants, preterm infants, sick infants, and mothers³

Sterile



- ✓ Validated manufacturing process according to standards^{1,4} for sterile medical devices
- ✓ Products treated with EO-gas – certified as sterile for the entire shelf-life
- ✓ Single sterile packaging guarantees sterility for each individual product
- ✓ Single-use products for minimum risk of contamination over time



* Laminar flow housing with air quality similar to EN ISO 8 or clean rooms EN ISO certified class 7 or 8⁵

** Colostrum Container only available as a sterile version

Ready-to-Use

Medela Ready-to-Use products are a hygienically safe³ and cost-effective disposable product option for all hospitals where the use of a non-sterile product is allowed.



Often local guidelines or regulations do not require sterility or the use of sterile products when it comes to human milk handling. As an example, processes such as pasteurisation rather than sterilisation are used as a norm for donor milk. Therefore, Medela recommends Ready-to-Use products as the best hospital solution for human milk pumping, collection, storage, handling and feeding.

The manufacturing processes yield Ready-to-Use finished products that do not require any further cleaning steps by means of physical or chemical methods. These extra steps have been rendered unnecessary since the hygienic production leads to an average level of colony forming units per product between 0 and 0,2⁶. The limitation level assures that Ready-to-Use products are more than 10 times cleaner than bottled water². Samples from every LOT are microbiologically tested to assure this low bacterial load and the absence of relevant pathogenic bacteria⁶. Furthermore, they have been approved for sick infants, preterm infants, term infants, and their mothers³.

EO sterile

Medela sterile products are validated as sterile according to the standards⁴ for medical devices EN ISO 11607-1, EN ISO 11607-2, EN ISO 11135-1. Single sterile packaging guarantees sterility for each individual product until the packaging is opened or damaged, or the expiry date is reached.



Sterilisation is a term referring to a process that eliminates all forms of microbial life to a non-significant level. The sterilisation process is expensive and many times not needed. Sterile consumables are to be used in those cases in which local regulations or guidelines require sterility.

References

- 1 EN ISO 11737-1: Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products.
- 2 Federal Ministry of Justice. German legislation for the quality of water intended for human consumption (Trinkwasserverordnung – TrinkwV 2001) (2001).
- 3 German Consulting Centre for Hospital Epidemiology and Infection Control (Deutsches Beratungszentrum für Hygiene). Conclusion of the Risk Assessment of the Production Method for Ready-to-Use Products (2014).
- 4 EN ISO 11607-1: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems, EN ISO 11607-2: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes, EN ISO 11135-1: Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- 5 EN ISO 14644-1 Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration.
- 6 Medela. CFU limitations for Medela Ready-to-Use products (Monitoring data 2014).

Products may not be available in all countries. For further information about Medela products, visit www.medela.com and look for location finders in your country or contact your local Medela representative.

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