

CFU limitations for Medela Ready-to-Use products

The production and packaging process as well as the microbiological checks that are carried out before the release of each product LOT guarantee, that there are only a safely low number of nonpathogenic germs, and overall, no pathogenic germs on the products. The applicable CFU (colony-forming unit) limitation levels for Medela Ready-to-Use products have been derived from the German legislation for the quality of water intended for human consumption¹. They are continuously monitored per production LOT in accordance with EN ISO 11737-1². In practice, the bioburden of each LOT of products is tested against the limitation level (CFU/product) by means of sample testing before

release for sale. The achieved average level of CFUs per product during the year 2024 and the limitation level for each product are shown in Table 1.

Moreover, microbiological checks that are carried out before the release of each product LOT guarantee that there are no pathogenic bacteria on the products (Table 2). In accordance with the German Consulting Centre for Hospital Epidemiology and Infection Control (Deutsches Beratungszentrum für Hygiene) the following bacteria are considered as pathogenic for term and preterm born infants (Table 3)³.

Ready-to-Use

Products intended for use in hospitals and clinics.

There is no need for cleaning prior to first use.

- Production and packaging take place in a clean room or under laminar flow⁴
- Formed at over 150 °C
- Every LOT is microbiologically tested before release²
- More than 20 times cleaner than bottled water¹
- Hygienically safe for use for term, preterm and sick infants as well as their mothers⁵



Article number	Article name (Containers)	Limitation level (CFU/product) ⁶	Achieved average levels (CFU/product) ⁷
200.2957	Ready-to-Use Single-Use Bottle 80 mL	28	
200.2956	Ready-to-Use Single-Use Bottle 150 mL	53	0.1
Article number	Article name (Symphony Pump Sets)	Limitation level (CFU/product) ⁶	Achieved average levels (CFU/product) ⁷
101047648	Ready-to-Use One-Day Symphony Pump Set size XS (18mm)	24	
101044745	Ready-to-Use One-Day Symphony Pump Set size S (21mm)	24	
008.0276	Ready-to-Use One-Day Symphony Pump Set size M (24mm)	24	0.5
008.0277	Ready-to-Use One-Day Symphony Pump Set size L (27mm)	24	
008.0278	Ready-to-Use One-Day Symphony Pump Set size XL (30mm)	24	

Table 1: CFU limitation level and achieved average CFU level

Article number	Article name (Containers)	Limitation level for pathogenic bacteria (CFU) ²
200.2957	Ready-to-Use Single-Use Bottle 80 mL	
200.2956	Ready-to-Use Single-Use Bottle 150 mL	0 per 36 bottles
Article number	Article name (Symphony Pump Sets)	Limitation level for pathogenic bacteria (CFU) ²
101047648	Ready-to-Use One-Day Symphony Pump Set size XS (18mm)	
101044745	Ready-to-Use One-Day Symphony Pump Set size S (21mm)	
008.0276	Ready-to-Use One-Day Symphony Pump Set size M (24mm)	0 per 36 pump sets
008.0277	Ready-to-Use One-Day Symphony Pump Set size L (27mm)	
008.0278	Ready-to-Use One-Day Symphony Pump Set size XL (30mm)	

Table 2: Limitation level for pathogenic bacteria for Ready-to-Use products

Pathogenic bacteria	
I Escherichia coli	I Streptococcus pneumoniae
I Enterococcus spp.	I Streptococcus pyogenes (A-Streptococci)
I Pseudomonas aeruginosa	I Staphylococcus aureus
I Shigella spp.	I Corynebacterium diphtheriae
I Salmonella spp.	I Clostridium botulinum
I Yersinia spp.	I Clostridium difficile
I Bacillus cereus	I Serratia
I Streptococcus agalactiae (B-Streptococci)	I Klebsiella

Table 3: Non-permissible pathogenic bacteria defined by the German Consulting Center for Infection prevention and Control (Deutsches Beratungszentrum für Hygiene) ³

References **1** Ministry of Justice, German legislation for the quality of water intended for human consumption (Trinkwasserverordnung, 2023 (2023)). **2** EN ISO 11737-1: Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products. **3** German Consulting Center for Infection prevention and Control, <https://www.bzh-freiburg.de/en/company> (Deutsches Beratungszentrum für Hygiene), Conclusion of the Risk Assessment of the Production Method for Ready-to-Use Products (2019). **4** Laminar flow housing with air quality similar to ISO 8 or clean rooms ISO certified class 7 or 8. ISO 14644-1 Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle Concentration. **5** German Consulting Center for Infection prevention and Control (Deutsches Beratungszentrum für Hygiene), Conclusion of the Risk Assessment of the Production Method for Ready-to-Use Products (2019). **6** Medela, CFU limitations for Medela Ready-to-Use products based on Federal Ministry of Justice, German legislation for the quality of water intended for human consumption (Trinkwasserverordnung 2023 (2023)). **7** Medela Monitoring Data 2024.