

Eppendorf Certificate

Certificate of quality

BioBLU® Vessels

The Eppendorf Quality Management System is certified according to ISO 9001, ISO 13485 and ISO 14001. For our customers, this converts into a constantly high and reliable quality of products and processes covering the complete product life time.

Environment and Production process

BioBLU Vessels are developed and manufactured according to ISO 9001, ISO 13485 and ISO 14001. Moulded parts are produced in a class 8 clean room environment according to ISO 14644-1. Machined components are free of potentially used auxiliary materials. Cleaning processes are controlled and monitored by the Eppendorf Quality Management. Final products are assembled under clean room conditions in a class 8 clean room environment according to ISO 14644-1.

The consistent reliable quality of BioBLU Vessels is ensured by monitored process controls and checks from the raw material to the final packed product.

Sterility and Endotoxins

BioBLU Vessels are sterilized according to ISO 11137 with an SAL level of 10^{-6} . Each lot is tested for the absence of pyrogens according to Ph. Eur. 2.6.14. For details please refer to the lot-specific certificates of the product.

Material

The raw material used to produce all BioBLU Vessels complies with USP Class VI <88>.

Statement on BSE/TSE

Materials of construction for Eppendorf BioBLU vessels are free of animal-derived components or comply with EMEA/410/01 Revision 3 (or equivalent regulatory requirements) for BSE/TSE mitigation.

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Leachables

Granulate suppliers of Eppendorf do not use or intentionally incorporate the following agents into the materials Eppendorf uses for the production of BioBLU Vessels:

- Tris(2,4-ditert-butylphenyl)phosphite (tDtBPP, Irgafos (R) 168)
- Slip agents (including oleamide, erucamide, stearamides)
- Biocides (including di(2-hydroxyethyl)methyldecylammonium salts (DiHEMDA))
- Plasticizers (including phthalates)
- Latex
- Antistatic agents
- Metallic dyes
- Mineral oil

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Page 2 of 2

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ISO 9001
Certified

ISO 13485
Certified

ISO 14001
Certified

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