

# 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

Hamburg, December 2014

Page 2 of 2

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ISO 9001  
Certified

ISO 13485  
Certified

ISO 14001  
Certified

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