

Eppendorf Certificate

Certificate of Quality

BioBLU® Single-Use Bioreactor

The BioBLU® single-use bioreactors combine advantages of single-use technology with the performance and scalability of stirred-tank designs, and can be applied to a wide variety of biological processes, including mammalian and stem cell cultivation as well as microbial fermentation. The BioBLU single-use bioreactors are intended to be used for Research and Development purpose only. Details see “Eppendorf Statement on Intended and Non-Intended Use for BioBLU® Single-Use Bioreactors”.

Quality Management System

The Eppendorf Quality Management System is certified according to ISO 9001, ISO 13485, and ISO 14001. A constantly high and reliable quality of products and processes covering the complete product lifetime is thereby established.

Environment and Production Process

BioBLU single-use bioreactors are manufactured in a controlled area and are subject to regular quality inspections. Manufacturing is continually monitored through stringent quality procedures. Consistent reliable quality of BioBLU single-use bioreactors is achieved by regular checks from the raw material to the final packed product.

Sterility and Endotoxins

Irradiation dose: min. 15 kGy [E-Beam]

Irradiation of BioBLU single-use bioreactors is carried out according to ISO 11137-2 with a SAL of 10^{-3} .

Each lot is tested for the absence of endotoxins according to Ph. Eur. 8.0 / 2.6.14. For details, please refer to the lot-specific test report of the respective product.

Please note: Sterility and Endotoxin statement is not applicable for the BioBLU® 3f (order number: 1386000900) which is not delivered sterile and needs to be autoclaved prior usage.

Additional Release Inspections

For each BioBLU single-use bioreactor, the following 100 % inspections are carried out during manufacturing:

- Visual inspection
- Integrity test (pressure hold test)
- Agitation test

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The following statements are valid for BioBLU single-use bioreactor components manufactured by Eppendorf (vessel body, head plate, impeller, and impeller shaft) as well as for the complete assembly process. On special request only, we may consent to supply additional information for third-party components, which is available for selected parts and products.

Biocompatibility

The raw materials used to produce the mentioned components of all BioBLU single-use bioreactors comply with USP Class VI <88> and/or respective sections of ISO 10993 standards.

Animal Derived Material - BSE/TSE

The raw materials of the mentioned components comply with EMA/410/01 Rev. 3 (or equivalent regulatory requirements) for BSE/TSE mitigation.

Production Aides and Material Additives

The above mentioned BioBLU components do not contain the following agents:

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

This Certificate of Quality is valid for the following BioBLU® versions (order numbers):

- BioBLU® 0.3c (78903507, 1386100200, 78903508, 1386100000); BioBLU® 0.3f (78903509, 1386100100); BioBLU® 0.3sc (1386100600)
- BioBLU® 1c (1386110000, 1386110100, 1386110400, 1386110500); BioBLU® 1f (1386110200, 1386110300)
- BioBLU® 3c (1386000100, 1386000300, 1386120000, 1386121000); BioBLU® 3f (1386000900)
- BioBLU® 5c (M1363-0125, M1363-0121); BioBLU® 5p (M1363-0119, M1363-0133)
- BioBLU® 10c (1386140000, 1386141000); BioBLU® 14c (M1363-0126, M1363-0122)
- BioBLU® 50c (M1363-0131, M1363-0129)

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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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