

Eppendorf Statement on Intended and Non-Intended Use for BioBLU® Single-Use Bioreactors

The BioBLU® single-use bioreactors, accessories and deliverables (subsequently referred to as “BioBLU products”) are, since its release to the market starting 2009, intended to be used in Research and Development purposes only (refer to operating manual “BioBLU® Single-Use Cell Culture Vessels and Adapter Kits”).

BioBLU products must be used in accordance with Eppendorf’s documentation and, if applicable, other associated supplementary terms (including without limitation, a research use only product label or limited use label license). In the absence of any intended use statement in the documentation or other supplementary terms associated with such BioBLU products, they are intended for research use only in bioprocessing applications and **not**, including without limitation, for medical use, clinical or diagnostic use, or direct administration into humans or animals.

BioBLU products are not submitted for regulatory review by any governmental body or other organization and are not validated for clinical or diagnostic use, for safety and effectiveness, or for any other specific use or application.

The customer is solely responsible for ensuring that the intended use of BioBLU products complies with applicable laws, regulations and governmental policies, and that BioBLU products are used by technically qualified individuals.

Eppendorf, at its discretion may on limited basis agree to support the evaluation of suitability and usability of BioBLU products for a specific use with available documents and related tasks e.g. questionnaires or on-site audits. However, Eppendorf cannot guarantee to be able to fulfill every individual requirement requested.

Customer seeking to request additional support from Eppendorf for areas of non-intended use may make regional application and will be required to fully disclose details of application, regulatory and commercial details. Customers requesting additional assessment and support for applicational use outside of Non-Intended Use will require a signed “Disclaimer for Non-Intended Use - Eppendorf BioBLU® single-use bioreactors form” supplied by Eppendorf.

Eppendorf will not be held liable for any claims, warranty or compensation resulting from any non-approved, non-intended use of BioBLU single-use bioreactors.

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