

Certificate DE22/819945814

The management system of

**Merck KGaA**

**SGS**

Frankfurter Str. 250, DE 64293 Darmstadt

has been assessed and certified as meeting the requirements of

**EXCiPACT Certification Standard  
for Pharmaceutical Excipient Suppliers, 2021  
Good Manufacturing and Distribution Practices**

For the following activities

Manufacturing and distribution of organic and inorganic salts, organic and inorganic acids and bases, solvents and aqueous solutions for use as pharmaceutical excipients

Manufacturing and distribution of non-sterile dry-powder cell culture media for use as pharmaceutical auxiliary materials

This certificate is valid from 18 June 2025 until 17 June 2028 and remains valid subject to satisfactory surveillance audits.

Issue 4. Organization certified since 17 June 2019 and first certified by SGS on 09 March 2022.

This certificate is not valid without a valid ISO 9001 certificate.

Authorised by  
Pieter Weterings  
Certification Manager

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To whom it may concern

**Scope of EXCiPACT® certificate for Merck KGaA, Darmstadt, Germany site**

For the attached EXCiPACT® certificate DE22/819945814 released by SGS and valid from 18th June 2025 until 17th June 2028, we would like to share further details on the product portfolios covered by the certification.

Pharmaceutical excipients (as indicated in the audit report):

*“Manufacturing and distribution of organic and inorganic salts, organic and inorganic acids and bases, solvents and aqueous solutions for use as pharmaceutical excipients.*

*Remark: The pharmaceutical excipients are sold under the brand names EMPROVE® exp”, EMPROVE® bio”, “EMPROVE® ESSENTIAL” and “EMPROVE® EXPERT.”*

Pharmaceutical Auxiliary Materials:

*“Manufacturing and distribution of non-sterile dry-powder cell culture media for use as pharmaceutical auxiliary materials”*

Cell culture media (CCM) covered by the above-mentioned certificate are exclusively solid or compacted dry-powder media, classified as Pharmaceutical Auxiliary Materials according to EXCiPACT®:2021 - PAM guide, and allocated to M-Clarity™ segment MQ500. Production and distribution take place at Darmstadt. The production is non-sterile, so Appendix I of the PAM guide 2023 Version 1 does not apply.

As stated on the label, our certified pharmaceutical auxiliary materials are not for direct animal or human use.

Excluded from the scope are Fast Track cell culture media (initial non-GMP CCM samples on customer request) and Cultured Meat Media (intended for food applications).

Sincerely,

Life Science - Quality Services

*This document has been produced electronically and is valid without a signature.*

*Date: May 14, 2025*