



Certificate of Compliance

InSphero AG

Wagistrasse 27a
8952 Switzerland
www.insphero.com

Product names

Akura™ 96 Plate
Akura™ 384 Plate
Akura™ PLUS Hanging Drop Systems

Quality Management System

Accredited in compliance with the current version of the ISO 9001 standard.

Animal Content

Product does not contain materials of animal origin.

Sterility

Product is sterilized and released dosimetrically by a validated process in an expert facility, accredited in compliance with the current versions of SN EN ISO 9001, SN EN ISO 14001, BS OHSAS 18001. This facility guarantees treatment of products according to ISO 9001, ISO 13485, ISO 11137 and 21CFR Part 820.

The bioburden prior to irradiation was verified according to ISO 11737, supporting a Sterility Assurance Level (SAL) of 10^{-3} of the irradiated product.

Samples of each irradiation lot are independently verified by a licensed expert test laboratory accredited in compliance with ISO 17025 to confirm absence of microbial growth according to ISO 11737.

Tissue culture

Each lot of irradiated product is tested for the ability to promote growth and formation of 3D cellular spheroids and organoids of mammalian and human suspension cells in culture.

Quality Control Testing

Every plate is visually inspected by InSphero prior to irradiation to guarantee integrity of plate design and acceptably low fiber background. Samples of each plate lot are tested after irradiation for ability to promote growth and formation of 3D cellular spheroids and organoids of relevant biological size and viability (cellular ATP levels).

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July 28, 2021/ Marion Bavand/ Head QA & General H&S