

Wertheim, 22/02/2021

Product Information

Product: Adapter for PD-Tips, BIO-CERT®

Cat. No.: 702399

Herewith we certify that the above mentioned BIO-CERT® product is manufactured from high-quality, pure granules under cleanroom conditions according to ISO 14 644-1 class 8 and is packaged automatically.

The product specified above is certified to be sterile, free of DNA, RNase, endotoxins and ATP.

Sterility:

BIO-CERT® products are sterilized according to ISO 11137 and AAMI guidelines with β -radiation, using a minimum radiation dose of 12.1 kGy. This gives a SAL (Sterility Assurance Level) of 10^{-6} . The sterility meets USP and Ph. Eur. requirements.

Free of DNA and RNase:

BIO-CERT® products are DNA-free ($< 4 \times 10^{-14}$ g/item) to prevent false positive signals during PCR applications. These products are free of RNases ($< 8.6 \times 10^{-15}$ g/item) to prevent degradation of RNA during purification processes.

Products are tested for Pyrogenic Endotoxin levels by following protocol:

A representative sampling of the product is extracted according to a procedure outlined in the USP in pyrogene water and the extract solution is then assayed along with positive and negative controls. The endotoxin concentration is tested according to Ph. Eur. by a gel-clotting Limulus Amebocyte Lysate (LAL) test. The detection limit is 0.01 EU/ml providing a documented endotoxin level of less than 1×10^{-12} g/item.

Free of ATP:

All products are supplied with a Certificate of Analysis which guarantees an ATP concentration less than 1×10^{-15} g/item. Therefore, BIO-CERT® products are suitable for ATP detection using bioluminescence-systems.

All lots are tested for sterility and endotoxins by an independent accredited testing laboratory and monitored for DNA-, RNase- and ATP-concentration.