

Product: CulturePro™ Dish
Catalogue No.: 16352
Lot No.: C-P8-2109-1
Manufactured: September 2021

We hereby confirm that the LOT indicated above will be validated in accordance with the following tests. Before final release for distribution the product has to pass all tests with acceptable results:

Sterility Sterility is obtained through irradiation according to ISO 11137 with SAL 10^{-6} . Caution: Only contents of unopened or undamaged packages are guaranteed sterile.

Cytotoxicity The product has successfully passed cytotoxicity testing in accordance with the USP, Method <87> and ISO 10993-5.

Embryo toxicity Blastocyst formation rate larger than 80% for fully expanded blastocysts both in test and control after 96 hours. The embryo toxicity test is a release test and the product will only be sold if it has passed satisfactorily.

The product is CE Marked according to EU directive, 93/42/EEC for Medical Devices.

Quality assurance of the product is performed in accordance with the requirements of the Quality Management System DS/EN ISO 13485:2016, "Medical devices - Quality management systems - Requirements for regulatory purposes".



Torben Christian Christensen
QC&RA Manager

Red colour of this dot indicates exposure to irradiation

