

GMP- and Cleanroom-Compatible CO₂ Incubator CellXpert® C170i



The CellXpert C170i CO₂ incubator from Eppendorf is a third party certified ISO class 4 / GMP grade A cleanroom compatible CO₂ incubator. It supports cell culture work in GMP and GLP environments with the following features and certificates (available upon request):

ISO class 4 / GMP grade A cleanroom compatibility according to ISO 14644-1

- > Third party certificate available (Fraunhofer Institute for Manufacturing Engineering and Automation IPA)
- > Tested in compliance with ISO 14644-14

Extended production certificate of quality, including:

- > Detailed performance results achieved during production test plus references and specifications
- > Calibration curves for heating circuits and high temperature disinfection (HTD)
- > Serial number, software version, configuration of tested device
- > Specification of test equipment used

Cleaning recommendations & chemical resistance overview

- > Recommendations for daily, weekly, monthly, and bi-monthly checks
- > Chemical resistance of device parts to various cleaning reagents

Effectiveness of high temperature disinfection (HTD)

- > Third party certificate available (Eurofins BioPharma Product Testing Munich GmbH)
- > Tested for bacteria, yeast, and other fungi

Material of construction (MOC) list, including:

- > Material code, material grade, AISI/UNS code
- > List of disinfectants tested for use
- > Cytotoxicity test of materials: passed (ISO 10993-5:2009)

Temperature homogeneity certificate (DIN 12880)

- > Temperature verified at 27 (9 per shelf) spots inside based on German Standard DIN 12880

Parameter and event data log plus export, including:

- > Set parameters, timestamp for parameter changes, timestamp for experiment critical events
- > Device serial number, software version, hardware configuration

More GMP- and cleanroom-relevant features:

- > Fanless design
- > Sterilization method
 - > 2h 180 °C, dry heat
 - > Illustrated step-by-step instructions on screen for standardization
 - > Downloadable performance protocol
- > Deep-drawn chamber (no weldseams) – stainless steel (Figure 1) or copper
- > Copper available for critical parts (water tray, shelves) (Figure 2)
- > Non-lamellar door seal to prevent mold formation
- > All interior parts sterilizable (e.g. no fan-associated, heat-sensitive internal HEPA-filters)
- > Fully removable water tray for weekly cleaning before refilling
- > 4/8-segmented inner doors available (Figure 3)
- > User management to restrict access to change parameters or start high temperature disinfection
- > Door lock (retrofittable to all CellXpert C170i produced after January 2022)
- > Noise level test for fanless design
 - > Third party certificate available (TÜV Nord Umweltschutz GmbH & Co. KG)
 - > Less than 30 dB(A) sound power level L_{WA}

IQ/OQ GxP Services, including:

- > Functional and alarm checks
- > Verification of instrument parameters
- > Detailed IQ/OQ report
- > Handling of deviation list/management

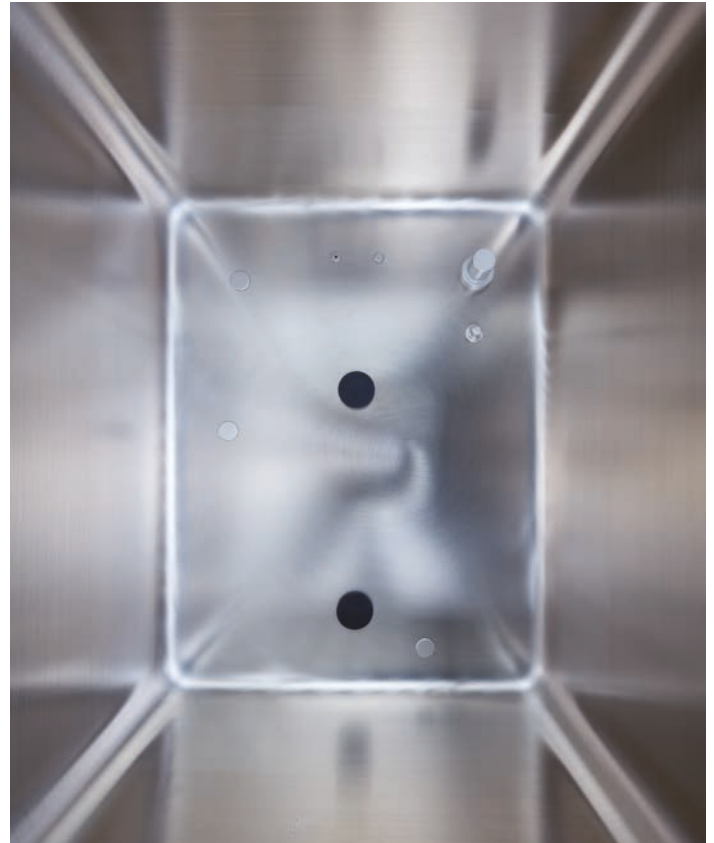


Figure 1: Fanless, deep-drawn stainless steel chamber with no weld seams



Figure 3: 4/8-segmented inner doors available



Figure 2: Copper chamber with available copper water tray and shelves

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