GMP- and Cleanroom-Compatible CO_2 Incubator Shaker CellXpert® CS220





The CellXpert CS220 from Eppendorf is a CO_2 incubator shaker compatible with ISO Class 7 / GMP Grade C under standard operating conditions. It supports cell culture work in GMP and GLP environments with the features and certificates listed below (available upon request).

Suitable for use in cleanrooms up to ISO Class 7 / GMP Grade C during standard operation at 37 °C
> Third party certificate available (TÜV SÜD)
> Tested in compliance with ISO 14644-14
> More information on request

Extended production certificate of quality, including:
> Clear identification: serial number, software version, and configuration
> Detailed performance data from testing, including references, specifications, and temperature verification curve
> Specification of the test equipment used for verification

Temperature homogeneity
> Verified by temperature mapping of five locations on the platform according to German standard DIN 12880:2007-05

Effectiveness of 180 °C sterilization
> Third party certificate available (Eurofins BioPharma Product Testing Munich GmbH)
> Proven to achieve > 6 $\log_{10}$ reduction of *Bacillus atrophaeus* spores (biological indicator for validation of dry-heat sterilization), *Candida albicans* and *Aspergillus brasiliensis*

Material of construction (MOC) list and chemical resistance overview, including:
> Material code, material grade, and AISI/UNS designation
> List of disinfectants tested and approved for use
> Cytotoxicity of materials (ISO 10993-5:2009): passed
> Chemical resistance of device components to commonly used cleaning agents

Parameter and event data log plus export, including:
> Direct view on user interface or download timestamped parameter and event log data, including serial number, software version, and hardware configuration
> Ethernet interface for external monitoring with VisioNize®; network-based connectivity to third-party systems may be implemented by the operator

Fast and easy routine wipe disinfection:
> Hygienic design according to DIN EN ISO 14159:2008
> Only few quick-removable, internal parts – no drive wheel, crevices, cover sheets, cables, or heating fins inside
> Glide up door and chamber depth of just 58 cm / 22.8 in for easy access even the back wall of the chamber



Figure 1: Fanless, deep-drawn stainless steel chamber without weld seams is compatible with standard disinfectants, including 70% isopropanol and ethanol.



Figure 2: Integrated 180 °C sterilization routine

More GMP- and cleanroom-relevant features:

> Deep-drawn, stainless steel chamber with no weld seams (Figure 1)
> Fanless design
> No speed limitation in stack: 20–300 rpm with 2.54 cm (1 in) orbit, 20–250 rpm with 5.1 cm (2 in) orbit
> Sterilization method
  > 2h 180 °C, dry heat according to international Pharmacopoeia requirements
  > Illustrated step-by-step instructions on screen for standardization
  > All chamber parts are sterilizable
  > Heat-resistant dual-channel IR CO_2 sensor
  > Downloadable performance protocol
> No cables inside the chamber for reduced risk of damage or handling accidents
> Non-lamellar door seal to prevent mold formation
> Condensate prevention by six-sided direct heating and dehumidification function
> Access port (30 mm) for inserting external sensors
> Alarm relay output for connection to a building management system (BMS)
> Create operation records per experiment/batch capturing key device information, parameters, user, performance, etc. – up to 1,000 non-editable records stored, exportable as PDF for GMP-compliant documentation
> Role-based user management with three defined access levels and individual password/PIN-protected accounts, including automatic logout after a pre-defined period of inactivity
> Set recurring tasks such as cleaning intervals or water refills for standardized procedures

IQ/OQ GxP Services, including:

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

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