



CLEANING SOLUTIONS



# cGMP Cleaning Systems

## PDC Fact Sheet

# Automation

## Application

For the efficient and validated cleaning of various equipments, which are used in the manufacturing process, the cleaning and the drying with the PDC meet the latest EHEDG and cGMP regulations. The complete PDC cleaning device and its procedure is designed, manufactured and documented in order to guarantee the personal safety as well as the unit protection.

## Description

The PDC is the validable solution in response to incoming requests in the automatic internal cleaning process of various equipments, which are used in the manufacturing process of pharmaceuticals, diagnostics, cosmetics and food industries. The PDC cleaning devices are for cleaning in batches. The cleaning steps with liquid medium are circulated and fully drained after each phase. For the inward transfer of the cleaned equipment in a higher classed room, the PDC is performed as a pass-through cleaning device. In which case, the doors are mutually locked and equipped with an efficient PLC and an interactive contact sensitive touch panel for a visible observation of the unit and its operating states, which also serve for the compilation of an individual cleaning program. For a fast requirement, the cleaning device provides up to ten menu-driven programmable cycles located on the start page of the touch panel. As standard, you have the choice between three PDC types: PDC 800, PDC1200, PDC1600. The necessary ceiling height for all types is 2900 mm. The required ceiling height can be reduced if the full admission height of 1000 mm into the cleaning chamber is not necessary. The maximum to be available space for the cleaning device is (W x D x H):

- PDC 800:  
800 mm x 800 mm x 1000 mm
- PDC 1200:  
1200 mm x 1200 mm x 1000 mm
- PDC 1600:  
1600 mm x 1200 mm x 1000 mm

## Dosing

## Wash Rack

## Cleaning

## Drying

## Qualification

## Validation



# Müller equipment cleaning device for validable cleaning and drying

## Features

**Control system.** A programmable logic controller PLC with all essential components and a colored contact sensitive touch panel provide a secure and quick operation of the cleaning machine. The cleaning programs are composed of phase modules which make it possible to choose the parameters of water quality, detergent, time, temperature, conductivity and other key process parameters. Various cleaning recipes for different equipment and residues are easy to create and store over operator interface. Accidental access is prevented due to different protection levels. All events are recognized in the audit trail.

**Doors.** The PDC is, depending on the application, equipped with one or two double glass doors. They consist of hardened glass with a revolving, inflatable seal, which seals the doors into the cleaning chamber by radial and gas tightening seals. The seal is pressure controlled during the whole cleaning process. The lift gate opens pneumatically and remains for each process step in any defined environment.

**Loading and unloading with transport cart and wash rack.** The loading and unloading is done by means of transport cart and wash rack into the cleaning chamber. Transport cart and cleaning chamber are the combination of an identical rail system, so that they build an enclosed rail system. This allows very easy and safe loading and discharging of the wash rack. Furthermore, the wash rack stops automatically at the correct position in the chamber.

**Inlet ports for process medium.** On the cleaning device there is only one type of inlet port, because the distribution of the medium is done only by one innovative valve assembly. All feed connections occur from the top. The connections contain the electrical power, a pneumatic supply unit, four



possible detergents as well as the connection for three water qualities and the processed compressed air required to blow completely dry the connections. The drain is at the lowest point of the device.

**Service doors and panels.** The service door on the front side provides access to the electrical and pneumatic components as well as to the detergent pumps. The sampling valve on the front side is easily accessible. The sheetings located left and right of the device, are removable without tools.

**Detergent metering pumps.** The provision of up to four diaphragm detergent pumps, level sensors and suction lance with screen and also storage place for detergent containers is standard. The metered detergent volume can be set by percentage in the cleaning program. By default electronic diaphragm piston pumps are included.

**Cleaning chamber and piping.** The cleaning chamber as well as the piping are drainable of all the residues. The slope of the ceiling and the bottom

plate of the chamber are over 3%, in order to allow a rapid liquid drain off. The radius of the corners of the chamber is over 30 mm. All components in the chamber are plugged and easily removable, as a matter of fact there are no threads used in the product contact environment. The employed rotary wings at the top and at the bottom of the chamber are furnished with pluggable end caps in which a magnet is tightly enclosed. By means of the magnets, the number of revolutions of the rotary wings are monitored through the PLC. The material touched by the product is manufactured of stainless steel 1.4404 / 1.4435. Chamber steel sheet surface quality is mirror polished EN 10088 2P. The piping in the chamber is provided with sterile clamp connections ISO DIN 11864 (T3). All sensors are EHEDG and are provided with Varivent® connections. In order to allow the complete non dead leg design of the chamber, only T-membrane valves are used in the pipes. The membranes consist in PTFE / EPDM.

**Process medium heater.** The heating of the process medium water and air occurs through a tube bundle heat exchanger, which in the piping (inline) heats and adjusts the temperature of the process medium, with steam or electricity. All parameters are stored in the cleaning program. For the thermometry a PT1000 and a PT100 are used.

**Drying air processing.** The necessary air for drying is produced through a side channel blower with a volume of 400 m<sup>3</sup>/h and pressure from 150 mbar up to 250 mbar, depending on the installation. Before the air is injected into the pipe, it is passed through a H13 filter. The filter is controlled with a differential pressure manometer and the message is clearly written on the touch panel.

**Insulating.** The chamber is insulated with asbestos-free and chlorine-free insulating blanket in order to limit the heat dissipation to the outside.

**Instrumentation tags.** All tags are characterised according to the Müller AG Cleaning Solution standard protocol.

**Factory acceptance test (FAT).** The standard factory acceptance test includes the verification of the standard configuration and the accessories on the basis of the user requirement specification (URS). Installation and operation tests (IQ/OQ) are held according to the Müller Cleaning Solutions standard protocol.

Tube bundle heat exchanger



#### Validation documentation

The PDC cleaning device is provided with the following standard documents:

#### Operator manual with technical documentation

- Operating instructions
- CE-conformity declaration
- List of proposed spare parts
- Layout plan
- P&ID-Schematic
- Spec sheets
- Electro schematic
- Pneumatic schematic

#### Qualification documentation

- Introduction
- Project information / description
- Order confirmation
- Specification of the whole device
- Project drawings
- Parts data sheets with certificates (2.2) and CE-conformity
- Parts list
- System Test Report (Protocol for FAT)

#### Safety features

- Main switch
- Emergency stop
- Pressure monitoring of the compressed air inlet
- Pressure monitoring of the door seal
- Door opening only possible under 60°C
- Push button with safety function for closing the chamber door
- Different access control levels (password protected)

#### Cleaning programs

The cleaning programs are changeable over a multiple choice drop down menu. The cleaning program configuration is simplified over predefined phases.

- Pre-washing
- Washing
- Neutralization
- Rinsing
- Evaporation (if available)
- Air-cleaning
- Drying
- Cooling

There are predefined selection screens for the mentioned phases:

- Which water quality (cold, warm or purified water) depending on the installation
- Which detergent; dosing feeder 1 to 4 (not possible in the rinsing process)



- Phase length; entering "minutes" in the time frame.
  - Phase temperature
  - Phase conductivity
  - Phase repetition (yes or no)
- The generated and saved cleaning program can be connected with an access key.

#### Utility requirements

- **Plant compressed air:** 7 bar, dry and oil free, connection Muffe 1/2".
- **Electricity:** 3 x 400 V, 50 Hz, 64 AMP fuse
- **Water:** flow rate 25 l/min with pressure of 1 bar. Up to four different water qualities connectable (standard), connecting pipe ISO DN 20
- **Steam:** pressure of the saturated steam of minimum 2 bar, flow rate 4 kg/min, connecting pipe ISO DN 20
- **Condensate:** 4 l/min, connecting pipe ISO DN 15
- **Drainage:** min. 50 l/min, non pressurised, connecting pipe ISO DN 80

#### Regulations:

- **FDA**
  - 21 CFR part 110: Food
  - 21 CFR part 210& 211: Pharmaceuticals
  - 21 CFR part 177: Non stainless steel parts
  - 21 CFR part 11: Electronic records
- **EHEDG**
  - Stainless steel in contact with process medium**
  - Material ANSI 316L, 1.4401, 1.4404, 1.4435
  - Material Certificates: 2.2 or 3.1

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