

CTH 36_48_72 C2

CYTOTOXIC DRUG CABINET



Introduction

Designed for the situation where is requested the operator, product and environmental protection from dangerous effects due to uncontrolled diffusion of air-transported contaminants and, in the same time, to avoid any biological interference from the environmental to the product during its handling.

Applications

Normally used in hospital pharmacies, oncology department, day-hospital and pharmaceutical industries.
For a correct use and application of the cabinet here described, it is necessary to refer to the appropriate standard norm and rules in force in the country where the cabinet is used. The main standard for product in Europe is a German Standard DIN 12980.

Definition

CTH C2 produced by ALS is a triple absolute filter cabinet and it is defined:
Class II as designed with a frontal working opening for the aspiration of 30% of the total air involved, at a minimum velocity of 0,40 m/sec., and the remaining 70% is recirculated through a HEPA filter in the working chamber with a laminar flow velocity between of 0,25 and 0,5 m/sec (as defined by DIN 12980 and by EN 12469).

Standards

CTH C2 cabinets produced by ALS is designed in according to DIN 12980 and EN 12469.

Performances

Operator Protection

The containment index, evaluated on the total surface of the front working opening, is equal or less than 5 CFU for not disturbance test or APF equal or more than 1×10^5 according EN12469.

Product Protection

Sterility in the working area higher than ISO Class 5 according to ISO EN 14644 (Class 100/M3.5 according to Federal Standard 209E) @ 0.3 and 0.5 μm particles.

Equal or less than 5 CFU per test, according product protection test EN12469 and

Equal or less than 2 CFU per test, according cross contamination test EN12469.

Environmental Protection

By filtration of the exhaust air through H14 HEPA filter with efficiency 99,995% MPPS as per EN 1822 (EU14 with efficiency 99,999% tested with DOP/DOS @ 0.3 μm).

It is suggested, except for particular cases, to duct outside the exhaust air as recommended by DIN 12980.

Norms and directives

The apparatus is developed in agreement with the following directives:

- 2006/42/EC Machinery Directive (when available)
- 2004/108/EC Electromagnetic Compatibility Directive (EMC)
- 2006/95/EC Low Voltage Directive (LVD)
- EN ISO 12100 Safety of machinery - General principles for design - Risk assessment and risk reduction
- EN 61010-1 Safety prescriptions for electronic measuring, control and laboratory equipment - general prescriptions
- EN 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements
- EN 12469 Performance criteria for microbiological safety cabinets

IMPORTANT !!

The apparatus doesn't reenter in the field of application of the directive CEE 93/42 about the medical devices, as it is deduced by the definition of "medical Device" at the art. 1 point 2 of the same directive.

ALS is not responsible for damages to people or things caused by an improper use of the system and, particularly, from the non-observance of the instruction of use and maintenance that accompany the same.

Technical Specifications

Work chamber and spillage tray in stainless steel AISI 304L "2B" finishing, smooth and sealed edges.

Working surface in stainless steel AISI 304L "2B" finishing, divided in solid sectors removable and autoclavable.

Front window, in laminated safety glass with camlock to provide an easier access for large items. The cabinet is provided of gas springs outside the contaminated area to keep the front glass open during maintenance or sanitization activities. Opening 150°.

Ergonomic front closure panel in stainless steel AISI304L complete of germicidal ultra-violet lamp.

Lighting on working surface by means of 2 fluorescent lamps of 39 Watt (36 version) or 54 Watt (48 version) or 80 Watt (72 version) fitted in non-contaminated area with electronic ballast.

Construction structure in steel epoxy-polyester powder coated, resistant to the most common industrial disinfectants.

Ventilation system by means of n°2 motor blowers dedicated to the one-way airflow in the working chamber, equal to 70% of the total involved air and the other dedicated to exhaust the remaining 30%.

The motor blower is centrifugal type, direct driven motor with double aspiration and protection factor IP55.

In case of failure of one fan, the other fan is able to guarantee, for period of emergency, a minimum efficiency of the protection of the front barrier.

Air filtration, both recirculate and exhaust air by means of two, in line, **H14 HEPA filters with efficiency 99,995% MPPS as per EN 1822**. All the filters (main, exhaust and intake ones) are tested with scanning method for integrity with DOP/DOS

Protection grid, for main HEPA filter made by anodized aluminium.



The 3rd stage of absolute filtration, under the working surface,

treats the whole 100% of the air to prevent contamination of cytotoxic product from the inside of the cabinet to parts like construction structure, motorblower and other components.

It is important to point out that sealing of recirculated and exhaust filters are guaranteed by sealing and negative pressure designed plenum. Sealing of the 3rd HEPA filter under working surface is guaranteed by sealing and by overpressure of sterile air area around it.

Command and Controls

Air ventilation control by means of automatic regulation of the revolution velocity of the motor blower. Two high-resolution flow rate volumetric devices, directly interfaced to microprocessor, achieve the automatic regulation. The microprocessor guarantees the activity of the motor blowers and controls the optimal function even in presence of effects caused by progressive clogging of the HEPA filters.

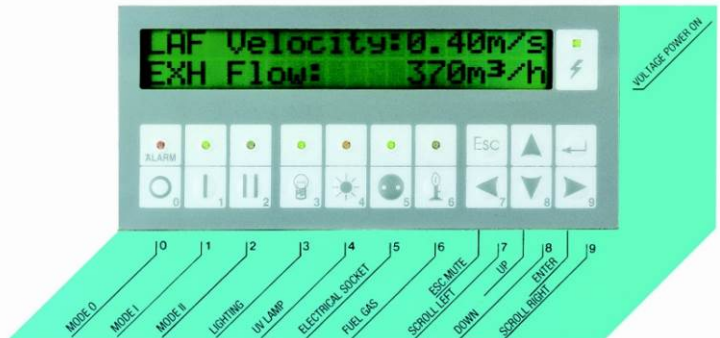
Alarm device optical (red signal light visible from working position and display message) and acoustic (buzzer) type, activated, at real time, by the **microprocessor**, with indication of type of alarm activate showing on a wide alpha numeric display.

Monitoring with alarms of the following parameters:

- Exhaust flow rate out of the pre-set range;
- Laminar air flow velocity out of the pre-set range;
- Front window in wrong position;
-

Alpha numeric display showing:

- Laminar air flow speed in m/s;
- Exhaust air flow rate in m³/h
- Date and time
- Hours counters for cabinet life
- UV Lamp run hours
- HEPA filters run hours
- Date of last HEPA filters change
- Date of last service
- Date of last power failure
- Change language
- Change password
- Setting UV timer program
- Setting MSC decontamination program



Tests control

Each cabinet is tested in our **Quality Control Dept.**, with the use of certified instrumentation and according to our internal quality as required by ISO 9001 certification.

On request validation test at site with IQ/OQ protocols are available

Standard features

- Fluorescent lights (n°2 T5 tubes) with electronic ballasts.
- Standard Italian and German duplex electric socket 4A IP 55 (internal back panel-right side)
- DOP/DOS 100% test inlet hose-barb port (internal under worktop - left side).
- Stainless steel AISI 304L front closure shield with germicidal lamp (15W and 30W respectively for 36 and 48 models), wavelength 253.7 nm (UV-C).

Optional features

- Vacuum air line with manual tap (internal back panel – right side) manufactured in compliance with UNI/CIG regulations, piping made of copper and hose-barb 10 mm diameter (external) for the connection to the main line.
- Gas line with manual tap (internal back panel – right side) manufactured in compliance with UNI/CIG regulations, piping made of copper and hose-barb 10 mm. diameter (external) for the connection to the main line. The gas line is provided with electrical automatic **safety valve** for interruption in case of electric blackout and/or ventilation failure.
- Compressed air line with manual tap
- Nitrogen line with manual tap
- Additional electrical power socket (right or left internal side)
- Activated carbon exhaust filter (h = 300 mm). With this optional item the cabinet can be ducted to outside, only after inspection of authorised ALS personnel.
- Double HEPA exhaust filter (h = 300 mm). With this optional item the cabinet can be ducted to outside, only after inspection of authorised ALS personnel.
- Interface RS485

Maintenance

The replacement of filters can be done from the front of the cabinet. Any other maintenance activity (control of the electric board, replacement of UV lamp) can be done from the front in non-contaminated area.

Ducting

The cabinet is designed to be ducted outside. The hereafter scheme is valid only for linear meter of smooth piping that can be directly connected, when requested, to the CTH C2. Each curve on the exhaust pipe causes a pressure drop of about one linear meter (Ex. 10 linear meters with 3 curves = 13 linear meters).

	<u>Duct Diameter</u>	<u>Max Duct length</u>
CTH 36 C2	mm 200	m 10
CTH 48 C2	mm 225	m 12
CTH 72 C2	mm 225	m 12

Technical characteristics

Model	Unit	CTH 36 C2	CTH 48 C2	CTH 72 C2
Code	--	ST-003014000	ST-003018000	ST-003145000
Overall dimension (WxDxH)	mm	1051x760x2402*	1356x760x2402*	1966x760x2402*
Safe working area dimension (WxDxH)	mm	883x500x685	1188x500x685	1785x500x685
Package dimension (WxDxH)	mm	1430x980x2200	1430x980x2200	2010x980x2200
Front opening dimension	mm	530	530	530
Max front opening high	mm	190	190	190
Net weight	Kg	300	400	500
Gross weight	Kg	330	430	550
System ventilation data				
Exhaust flow rate	m ³ /h	280	380	550
Heat emission at 25 °C ⁽¹⁾	Kcal/h	340	365	545
Noise level	dB (A)	≤58	≤62	≤65
Lighting	Lux	1000	1300	1330
Electrical data				
Voltage	V	230V AC F+N+P.E.		
Frequency	Hz	50		
Absorption ⁽²⁾	A	8	9	10
Electrical classification (with feeding cable)		1		
Protection category		IP 20		
Power socket (protected by a single fuse 4A)		2P+T 250V 10/16A IP 55		
Fluorescent lamps	W	2x39	2x54	2x80

*without floor stand: 1975 mm

⁽¹⁾ Only for cabinets that recirculate air in environmental

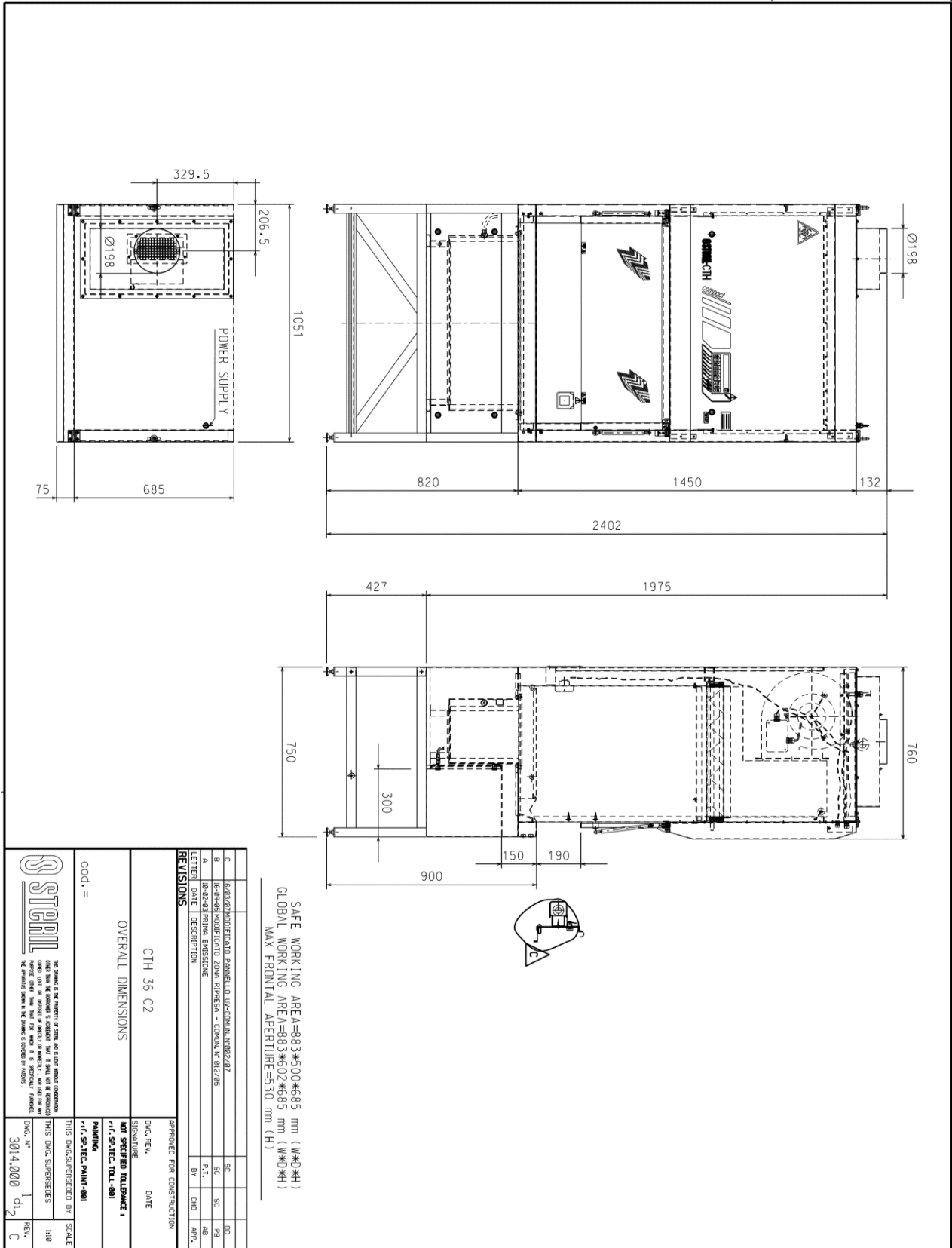
⁽²⁾ This value includes max absorption of power socket equal to 4A

Other technical data

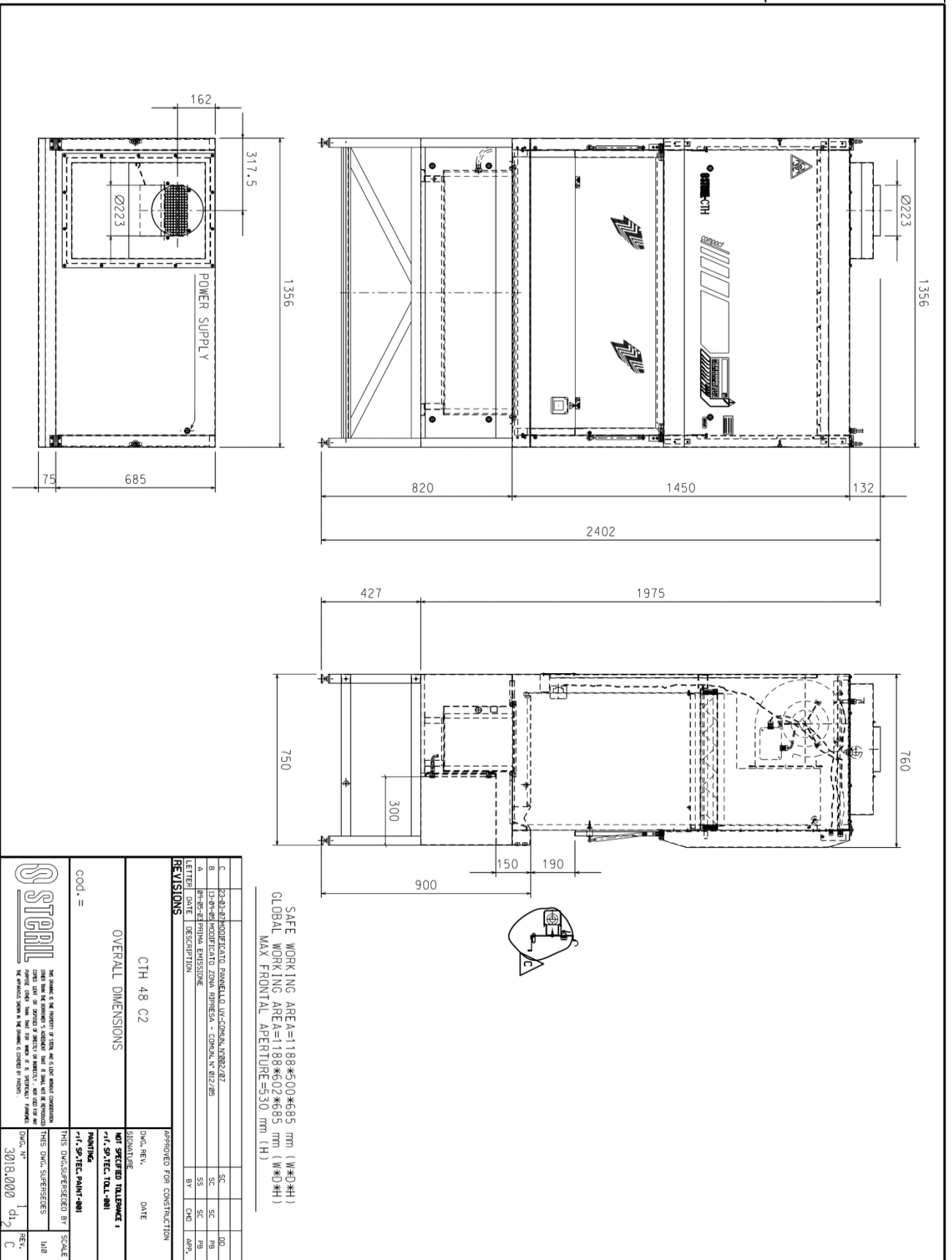
Product Name	CTH C2 series STERIL™ is a brand name who belong to ANGELANTONI Group.
Manufacturer	Angelantoni Life Science S.r.l. Loc. Cimacolle, 464 06056 Massa Martana (PG) - Italy
CE marking ref.	MACHINERY DIRECTIVE 2006/42/CE (if applicable) EMC DIRECTIVE 2004/108/CE LOW TENSION DIRECTIVE 2006/95/CE EN 12100, EN 61326-1, EN 12469, EN61010-1, 2011/65UE.
Power supply	208 – 253 VAC 50 Hz single phase
Ambient conditions of use	Temperature: +10° ~ +32° C Relative humidity: 30 ~ 85% without condensation
Stocking condition	Temperature: +2° ~ + 50° C Relative humidity: 20 ~ 80% without condensation
Alarms types	Acoustic and Optical
In case of power black-out	System OFF
Warranty	Twenty-four months from shipping date (valid on defective spare parts only)

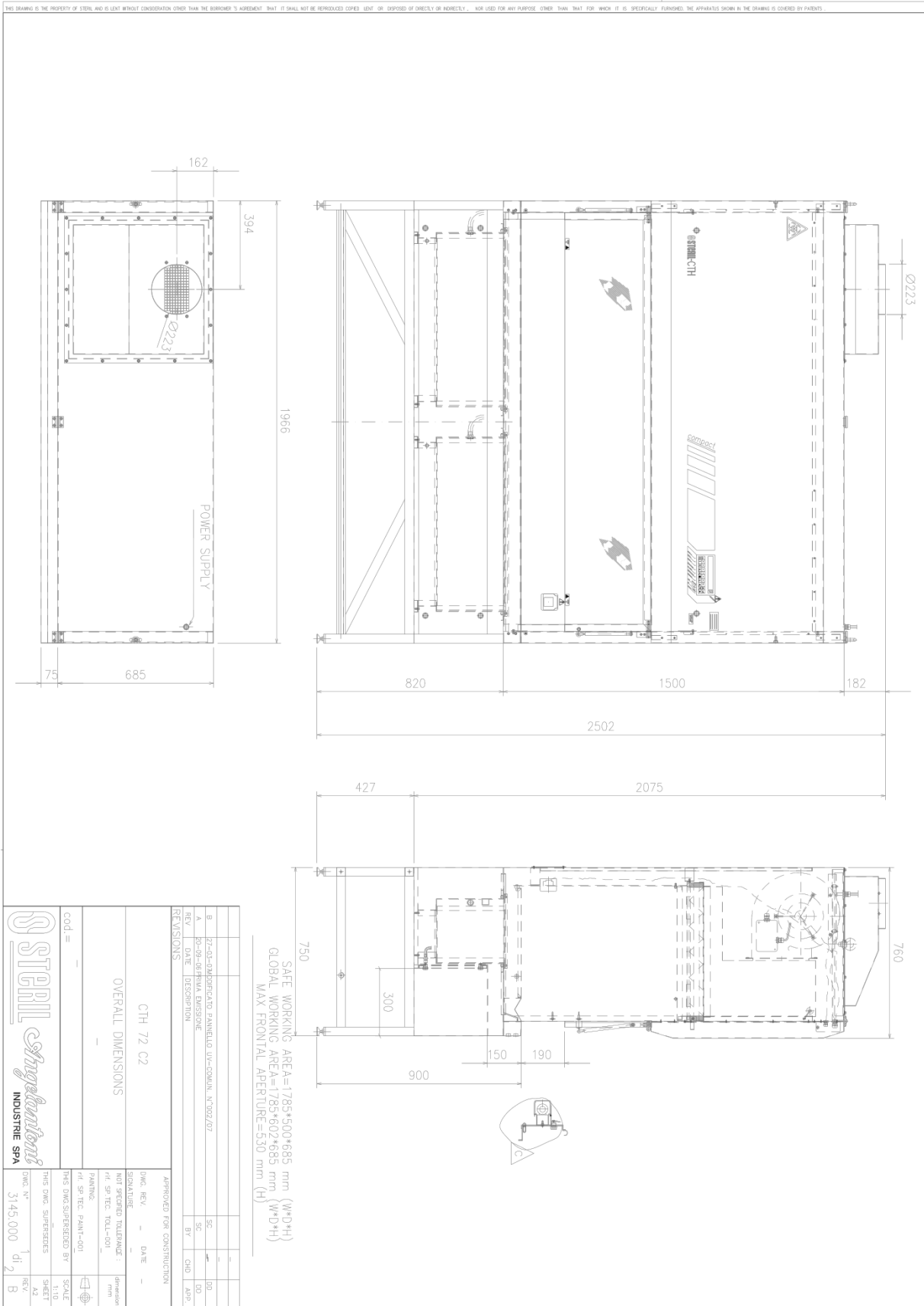
Reference layout

DWG N° 3014.000 1 di 2



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