

Pharmaceutical System Plants





Remoin in the world since 1982



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Since 1982

La Remoin srl nasce a Cisterna di Latina nel 1982, per la realizzazione e montaggio di impianti industriali per l'industria chimica meccanica.

L'Azienda

Nel corso degli anni l'azienda acquisiva quote di mercato sempre più ampie pertanto si è resa necessaria la realizzazione di una sede produttiva distaccata nel comune di Artena in provincia di Roma. Nel tempo, la Remoin si è specializzata nella progettazione e costruzione di impiantistica specifica per l'industria farmaceutica.

Oggi progetta e realizza impianti chiavi in mano di fluidi puri quali: sistemi di produzione, stoccaggio e distribuzione di acqua distillata WFI, acqua purificata PW, circuiti di distribuzione di vapore pulito, piping di processo, sale preparazione con gestione automatica delle ricette e sistemi CIP/SIP completi di sistemi SCADA specifici per l'industria farmaceutica, chimica e alimentare, secondo le prescrizioni raccomandate da ISPE FDA e c.G.M.P., GAMP 5, e CFR 21 part. 11.

Costruisce Distillatori multieffetto, Temocompressione, Generatori di vapore puro, Osmosi con EDI, Sistemi di lavaggio CIP/SIP, Preparatori e Dissolutori per principi attivi, Turbo Emulsori, Serbatoi di stoccaggio e Scambiatori di calore DTS per L'industria farmaceutica, chimica e alimentare, secondo le prescrizioni raccomandate da ISPE FDA e c G.M.P., e CFR21 part. 11.

La società è certificata ISO 9001 dal 1998.

Remoin Srl was founded in Cisterna di Latina in 1982, for construction and assembly of industrial plants for the mechanical chemical industry.

The Company

As the time went by, the Company increased its business and its market shares grew up constantly; therefore, it became necessary to set up a separated production facility in Artena, a town in the province of Rome. Over time, Remoin has specialized in the design and construction of industrial plants, specific for the pharmaceutical industry.

Today, Remoin designs and manufactures full turnkey plants of pure fluids, such as: production/storage & distribution systems for PW, WFI and PS, process piping, solution preparation rooms with automatic management of the recipes, and CIP/SIP systems. All of them are complete with specific SCADA systems for pharmaceutical, chemical and food Industries, complying with ISPE, FDA, cG.M.P., GAMP 5 and CFR21 part 11.

Remoin also manufactures Multi-effect Distillers, Thermo-compression Distiller, Pure Steam Generators, Reverse Osmosis with EDI, CIP-SIP systems, Preparation Tanks, Dissolvers for active ingredients, Turbo Emulsifiers, Storage Tanks, and Double Tube Sheet Heat Exchangers (DTS) for pharmaceutical, chemical and food industry complying with ISPE, FDA, cG.M.P., GAMP 5 and CFR21 part 11.

The company is certified ISO 9001 since 1998.







Reverse Osmosis

OSMO-REM

The units of OSMO-REM are available in various versions from 300 It/h to 6000 It/h (higher flow rates available).

Skid-mounted system for the production of Purified Water and Highly purified Water, in accordance with the Ph. Eur. And the US Pharmacopoeia.

The design allows each system to be pre qualified during the Functional F.A.T Test.

The OSMO-REM System is designed to purify water by letting it pass through the membrane. The fluid control provide a mean of managing flow rates and pressure, high flow rates and short regeneration cycles minimize microbiological growth.

The OSMO-REM modules allows hot water sanitization. Hot water prevents growth of Biofilms, with no need to rinse out with chemicals.

SPECIAL FEATURES:

- Design and realization according GMP Guidelines and recommendations of the ISPE Engineering guide and of the FDA.
- Parts in contact with the medium made of stainless steel SS 316L with Tri - Clamp connections, no dead zones and with a surface roughness < 0.6 μm.
- Continuous circulation to prevent bacterial growth when the tank is full.
- PLC controller Panel, capable of interfacing with a higher level control system, easy- to-use controller for the acquisition and processing.
- All systems they can be provide with EDI Module for the production of pure and highly purified water.
- All in a compact SKID MOUNTED made in stainless Steel 304.











Reverse Osmosis

OSMO-REM



- Temperature: working temperature ~15°C
- Flow speed: ~1 m/sec

TEST:

- According to project specifications
- According to project performance
- Materials, test and qualification certificates

PLC CONTROL:

- System operating report
 - Remote control by BUS
- Alarms

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- Set point

SERVICES:

- Commissioning
- Staff training
- Validation assistance
- On-demand services
- Maintenance and Supervision programs
- Replacement parts and consumables

STANDARDS & REGULATIONS COMPLY:

USP/FDA European Pharmacopoeia

APPLICATION:

- Drinking water production from brackish, solphurous or very mineralized water, which are not treatable for technical or cost reason
- Drinking water from sea water
- Feed water for distillers to industrial and pharmaceutical cleaning or process water production
- High pure water for electronic industry
- Production of dialysis liquid for hospital use

ON LINE INSTRUMENTS:

- Conducibility probe
- Flow meter
- Temperature probe
- Pressure gauge



Multi Effect Distiller

Mod. M-REM



REMOIN's multiple effect stills are indentified with the name **M-REM** and they can produce distilled water from a minimum of 100 lt/h to a maximum of 12.000 lt/h; anyhow, on demand, it is possible to supply distillers with a manufacturing capacity up to 20.000 lt/h.

The distiller is entirely built in stainless steel AISI 316L; all the inner surfaces in contact with th product have a roughness of $Ra \le 0.4 \mu$, they are pickled and passivated according to ASTM 967 rules and, as optional, also the electropolishing can be requested. All the external surfaces are mirror polished/satined.

The Hydraulic plant is realized with pipelines made of s.s. AISI 316L according to the ASTM A 270 and ASME BPE rules.

All the connection welding between pipes and fittings will be TIG realized by orbital automatic procedure and a printed report of them will be released. As optional, also the Boroscopy can be asked. Gaskets are sanitary type made of Teflon.

Distillers are supported by a tubular structure made of stainless steel AISI 304, satined. For the control and the management of the production, the distiller is provided with an electrical board with PLC/PC and operator interface.

The operation is completely automatic and gives the following possibilities:

- Sterilization of the plant after a long time of stop and before its new start;
- Continuous control of the conductivity of the distilled water produced and automatic discharge in case of insufficient clearness;
- Continuous control of the levels;
- Operation according to a weekly program of all the requested phases.









Thermocompression Distiller

Mod. M-REM-T



Thermo-compression distillers are briefly named M-REM-T and they can produce distilled water from a minimum of 50 l/h to a maximum of 5.000 l/h; it is also possible to supply distillers having a bigger production capacity, on customer request.

The Remoin M-Rem-T Thermocompression distillers always operate with an internal pressure higher than the atmospheric avoiding any possibility of outside air entering the plant.

In every distillation phase, the distillate is always at a pressure higher than the infeed water, thereby ensuring that in the likelihood of leakage of feedwater it will never enter the distillate circuit. The distillate leaves the plant at a pressure of 1,5 bar.

Distillers are completely stainless steel AISI 316L manufactured; all the inner surfaces, which are in contact with the product, have a roughness $Ra \le 0.4 \mu m$; all the surfaces are pickled and passivate and it is possible to require for electro-polishing optionally.





Thermocompression Distiller

Mod. M-REM-T

All external surfaces are satin / mirror polished.

Plumbing is made of AISI 316L pipes according to ASTM A 270 and ASME BPE rules. All the welds of connecting pipes and fittings will be made by TIG with orbital automatic procedure and printed report; it is also possible to require for boroscopy, optionally. Gaskets are sanitary type, Teflon made.

Distiller is sustained by a tubular satin frame in stainless steel AISI 304.

Distiller is provided with the electrical control board having PLC/PC and user interface (HMI) to control and manage the necessary phases. It works fully automatically and it gives the following chances:

- sterilization of the plant after long stop, before start up;
- continuous conductivity control of distilled water produced and automatic drainage if purity is not enough;
- continuous levels control;
- operation of all required phases, according to a weekly schedule.

Documentation provided by Remoin Srl together with plants includes all phases of project creating up to final tests at customer site, and it has all the information needed for plant validation (D.Q.; I.Q; O.Q; P.Q, instruments calibration and computer validation).

Our M-Rem-T distillers operate:

- with electrical heating
- with steam heating (3 bar)
- both with electrical and steam heating systems











Mod. RPS

Pure steam generator includes an exchanger with double plates DTS, vertical, and connected to a vaporization chamber, on whose head top a clearing parcel "Vicotex" is placed to avoid any drag of micro drops of water not evaporated and the following contamination of pure steam. The pure steam generator will be connected tri/clamp for all process connections, with a safety device at the overpressure consisting of a bursting disk with a support for the vacuum, PLC for a sequential control, high pressure high/low level, electro alarms, pneumatic diaphragm valve controlled by PLC, all mounted on a polished structure in Stainless Steel AISI 304.

The exchanger and the vaporization chamber are insulated by fibreglass with finish in Stainless Steel AISI 304 polished/pickled.

REMOIN pure steam generators can produce a minimum of 50 kg/hour, to a maximum of 4000 kg/hour.

Type of materials:

- Stainless steel AISI 316L/304L

Application fields:

- Pharmaceutical/chemical
- Food and Cosmetic

Surface finish:

- Internal: Ra ≤ 0,5µ
- Esternal: Satin/Mirror polished





Electrical Pure Steam Generator Mod. E-RPS









REMOIN is an industrial company specilized in the design and construction of Sanitary Tanks in stailess steel AISI 316L according to F.D.A. and G.M.P. standards. Our line of products goes from 50 Lt. to 60.000 Lt.. Horizontal or vertical execution with external thermal insulation in stainless steel AISI 304L. A satin finish produced by grinding all the weld and completely sealed.

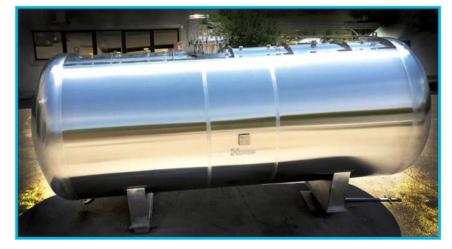
Type of employment: Distilled water - Purified water















Sanitary Tanks

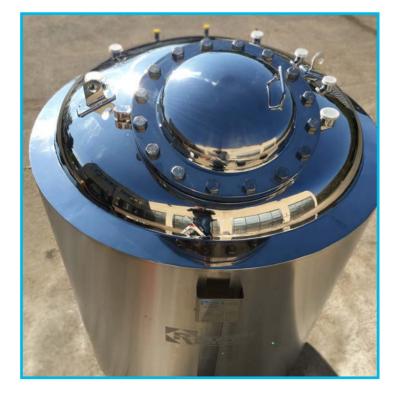
Surfage finish: Internal: Mirror polish Ra ≤ 0.3 (Optional electropolish) External: Satin or mirror polished















Exchanger DTS

REMOIN s.r.l. is an industrial company specialized in the research, design and construction of sanitary heat exchangers with double plates (DTS), built to avoid contaminations between primary and secondary fluid.

Realized in vertical or orizzontal, heated or cooled or with a combination of functions.

Single, double or multiple passage, and autodrained, isolated and steel in AISI 304, completely sealed.

Type of materials:

- Stainless steel AISI 316L/304L
- Hastelloy

Application fields:

- Pharmaceutical

- Cosmetic

- Biotechnologic

Technical data: - Straight pipes with double fixed plates

Surfage finish:

- Internal: mirror polished $Ra \le 0,3$, optional electopolished
- External: satin or mirror polished

Type of employment:

- Distilled and bidistilled water
- Purified water
- Pure Steam











Distribution Piping ASME BPE





LOOP PW - WFI & CS

REMOIN is a company specialized in the design and construction of 3A Sanitary piping in ASTM A270 according to FDA and GMP prescriptions:

- Loop Plants WFI (distilled water)
- CIP lines plants
- Loop Plants purified water
- Pure steam line plants
- Loop Plants demineralized water
- Process line plants
- Loop Plants osmosis)
- Gas line plants
- Solution Preparation Plants

The plants are equipped with all line accessories such as elbows, tees, reductions, ferrules, clamps and gaskets.

All fittings such as elbows, tees and reductions are drawn from tube with single casting so to avoid any differences of thickness and to obtain a better quality of the welding with automatic procedures.

As for piping systems **REMOIN** is also specialized in design and construction of control boards for the control of the WFI loop systems, PW loop, Demineralized water, osmosis loop, process plants, solution preparation and CIP plants.





Distribution Piping ASME BPE

OP PW - WFI & CS





12







REMOIN will issue for each plant, the technical documentation needed for cGMPs/FDA approval:

- WPS + PQR
- Welder license
- Automatic welding tests format
- Automatic daily welding formatCertificates of hydraulic test

- Certificates of passivation
 Certificates of X-rays/penetrant liquids
- Roughness certificates
- Dimensional certificates
- Slope certificates
- Conformity certificates
- Materials certificates 3.1B
- Boroscopic certificates
- Cerificates of slope
- Conductivity certificates
- Temperature certificates
- P&ID Drawings
- Assonometric drawings with identification of the welding
- Preparation and execution of protocols IQ, OQ





Distribution Piping ASME BPE







LOOP PW WFI & CS

















REMOIN is a company specialized in the design, construction, automation and validation of **Solution Preparations**, according to the FDA & GMP requirements. Our Solution Preparation are complete with preparers, sanitary piping made of stainless steel 3A ASME BPE and all the relevant accessories.











REMOIN makes also the electro-instrumental plant SCADA system with control board for the automatic control of PLC/PC of the system and it supplies all the technical documentation for the validation purposes.

































MOD. REM-SP LINE

REMOIN among the other things, is also specialized in designing, constructing and installation of Solution Preparation complete with Isolator, on proper skid, suitable to be in Sterile Areas Class A, B and C. Isolators are used in the production of oncological and injectable medicines; they are structured to operate both in positive and negative pressure, depending on the type of product to be treated.

The plant can be made with both fixed and mobile preparation tanks, complete with all the utilities at their service: WFI, clean steam, nitrogen, sterile air, thermostating, product lines. Isolators are designed to be able to handle products in a safe and controlled environment and can be sterilized with Hydrogen Peroxide (VHP). The material of Construction for all components is stainless steel AISI 316L ASME BPE SF1 or SF4. All welds are executed with automatic procedures and controlled by borescopes. All pipes and fittings are passivated according to ASTM 967.

The system is supplied complete with an electro-instrumental system and, on request, it can be monitored with SCADA; it complies with the CFR21 PART 11 Directives and the USP, cGMP and FDA Prescriptions.

MAIN CHARACTESTISTICS:

- Internal Design studied to facilitate cleaning and prevent accumulation of dirt;
- Integrated ejection system;
- HEPA H14 filters on intakes;
- Hepa H14 filters o outlets;
- System of holding and controlling Inflatable seals;
- Pressure control on Chamber and pre-chamber;
- Filters obstruction control;
- Doors made of crystalline PMMA (different materials on request);
- Oval Flanges for better ergonomics.

OPTIONALS:

- Inertization system
- Continuous particles control
- CIP/SIP







MOD. REM-SP LINE

REMOIN è una società specializzata, tra le altre cose, nella progettazione, costruzione e installazione di sale preparazione complete di isolatore, su skid, adatte ad ambienti sterili di classe A, B e C. Gli isolatori sono impiegati nella produzione di farmaci oncologici e iniettabili; essi sono strutturati per lavorare sia in pressione positiva che negativa, a seconda del tipo di prodotto da manipolarsi.

L'impianto può essere realizzato con preparatori sia fissi che mobili completi di tutte le utilities a loro servizio: WFI, vapore pulito, azoto, aria sterile, termostatazione, linee prodotto.

Gli isolatori sono progettati al fine di poter manipolare prodotti in ambiente sicuro e controllato e possono essere sterilizzati con Perossido di Idrogeno (VHP). Il materiale di costruzione per tutti i componenti è acciaio inossidabile AISI 316L ASME BPE SF1 o SF4. Tutte le saldature sono realizzate con procedimenti automatici e controllati con boroscopie. Tutte le tubazioni e i raccordi sono passivati secondo la normativa ASTM 967.

Il sistema viene fornito completo di impianto elettro-strumentale e, su richiesta, può essere monitorato con SCADA; esso è conforme alle Direttive CFR21 PART 11 e alle Prescrizioni USP, cGMP e FDA.

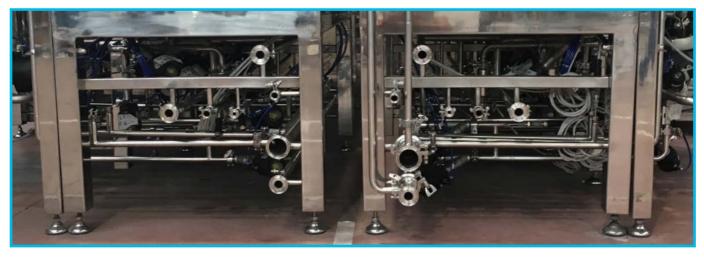
ALTRE CARATTERISTICHE PRINCIPALI:

- Design interno studiato per facilitare la pulizia e evitare accumulo di polvere;
- Sistema di eiezione integrato;
- Filtri Hepa H14 sulle mandate;
- Filtri Hepa H14 alle uscite;
- Sistema di tenuta e controllo guarnizioni gonfiabili;
- Controllo pressione di camera e precamera;
- Controllo Ostruzione dei Filtri;
- Porte in PMMA cristallino (altri materiali su richiesta);
- Flange ovali per una maggiore ergonomia.

OPTIONALS:

- Sistema di Inertizzazione;
- Controllo particellare continuo;
- CIP/SIP.







MOD. REM-SP LINE

















MOD. REM-SP LINE







Preparation Tanks

REMOIN is an industrial company specilized in the research, design and construction of preparation tanks according to F.D.A. and cG.M.P. standards.

All preparation tanks units are complete with: bottom valve, magnetic mixer with fast connection/disconnection, hand hole with fast opening/closing by wing nuts and sight glass with lamps, tri-clamp connections.

Our line of products goes from 5 Lt. to 30.000 Lt..

Vertical execution, single or double wall, interwall for heating or cooling or combination with external thermal insulation.

A satin finish produced by grinding all the weld and totally sealed.













Preparation Tanks

















Turbo Emulsifiers

REMOIN is a company who can engineer and build equipments turbo emulsifiers as tracked or fix for vacuum preparation of tooth paste, creams, oils, gel and sterile ointments. Small and medium scale capacities, having same features as the equipment engineered for high outputs.

The plant allows different configuration according to process requirements:

- Anchor agitator, with or without scrapers.
- Turbo-emulsifier fitting a wide range of heads to meet with any specific requirements of customers.
- Anchor with axial or planetary counter-revolving.
- Magnetic agitator with possibility of quick connection or disconnection.
- Dispersor in recirculation.



- Equipment for pharmaceutical-grade valves and fittings, 3A/FDA approved.
- Kettle valve.
- Flush mounted valve.
- Weighing system.
- Lifting column complete with mechanical and electronic securities.
- Thermostating unit with remote controls or main Control Board.
- Deaerating vacuum pump.
- Main Control Board with MPU control unit.
- Synoptic or control screen.
- Variable speed on all equipments installed.
- Parameters and events recording.
- Automatic and/or manual monitoring and execution of the process
- Stainless steel skid.

The machine is designed and engineered in compliance with the most demanding standards ruling on operator safety during process stages.

The machine basically features "IN-LINE" connection to automatic CIP and SIP washing and sterilization systems.

The extreme versatility of the machine allows handy and quick servicing thanks to the independence of each component installed. The use of the machine for sterile products and environments requires its compliance to cGMP in that it is manufacture and to 3A/FDA for the class of the material used.







Clean in Place System - Cip

REMOIN is a company specialized in the design and construction of plants for distillation, purification and treatment of water, as well as CIP systems.

Our Technical department cares for the design and the final execution of projects, in accordance with all the current rules and laws for each plant.

REMOIN Srl may provide process systems complete with integrated CIP/SIP, in order to give the proper assistance to the customers and grant them with a correct maintenance perfect efficiency and long life for plants, as well as in order to avoid misunderstandings concerning the interface with various suppliers of some parts of the plants.









Clean in Place System - Cip

System Configuration:

REMOIN Srl can design and construct a system that meets the customer's specific requirements.

CIP Systems configuration depends on the following:

- Single or multi-task
- Recovery of washing solutions and rinsing
- Return by pump or coming systems
- Final rinsing by WFI or DW
- SIP (Steam in place)

- Heating by direct injection of steam or heat exchangers
- Skid mounting
- Control and Maintenance of Conductivity with automatic addition of alkali/acids
- Automatic/Manual control integrated in the process, with supervision system
- Operation according to a weekly program of all the requested phases.

Materials and Finishing:

- Stainless steel AISI 304 or 316L, standard 180 Grit with options for 380 and electropolishing



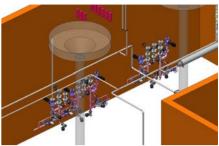


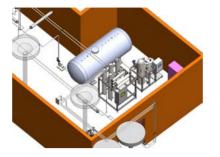


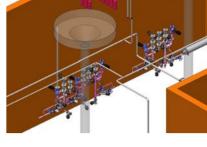
3D Project



REMOIN can develop 3D drawings, made by Solid Works, for PW loops, WFI loops, Pure Steam Distribution, Solution Preparation, CIP/SIP systems on Skid.







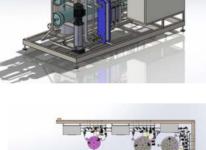




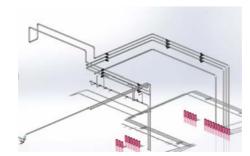




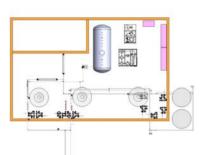


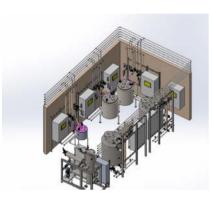




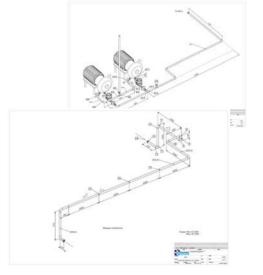












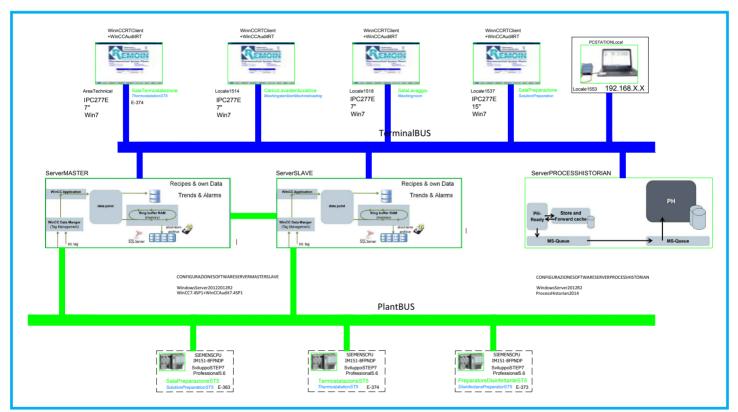




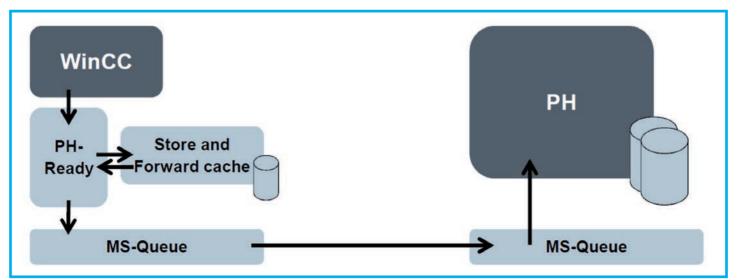
REMOIN can design and manufacture electro-instrumental/Automation plants complete with SCADA system. - WinCC

- iFIX
- Wonderware
- Movicon

Complying to all European and International Directives. All the systems also have CFR 21 Part. 11 license, Audit Trail and customized recipes complying to ISA 88 Standard.



SCADA System Flowchart



Representation of WinCC data flow - Process Historian

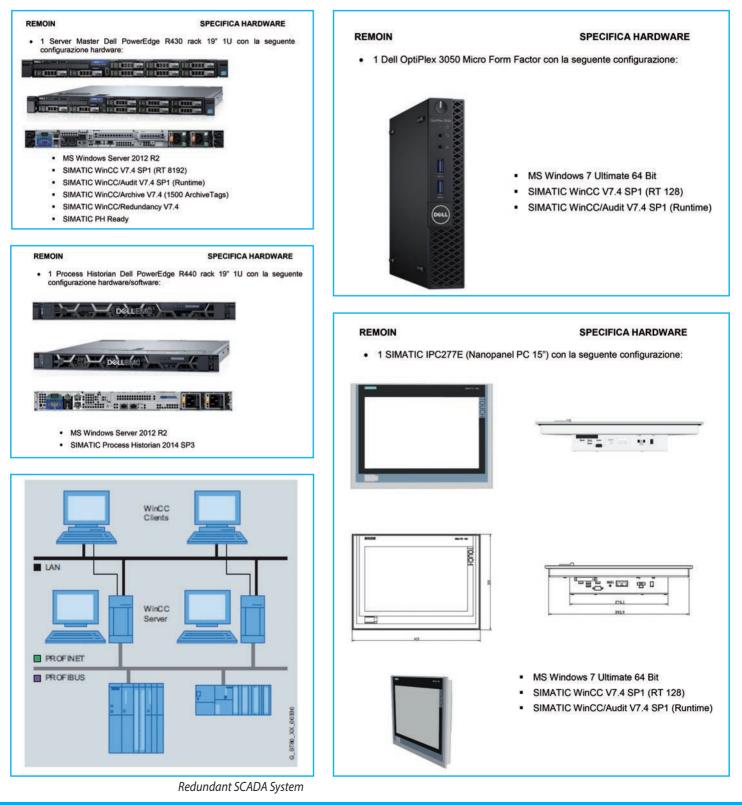




REMOIN è in grado di progettare e realizzare impianti elettro-strumentali/Automazione completi di sistema SCADA.

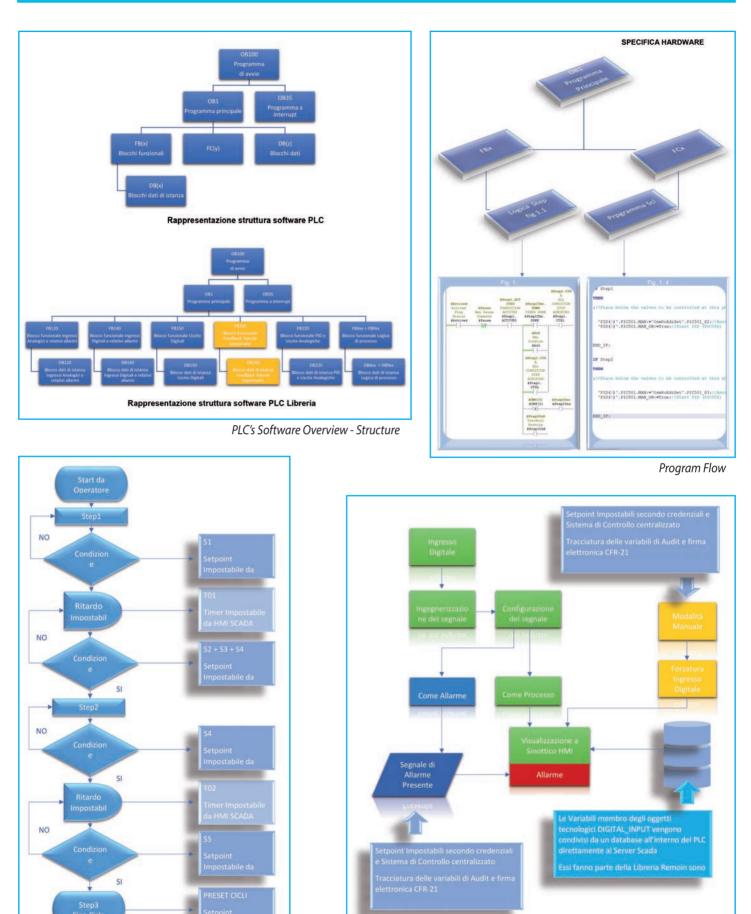
- WinCC
- iFIX
- Wonderware
- Movicon

Conformi a tutte le direttive di legge europee e internazionali, tutti i sistemi hanno anche licenza CFR 21 Part. 11, Audit Trail e ricette personalizzate conformi secondo standard ISA 88.





Automation System



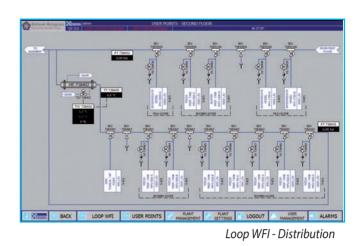
Hardware Specification

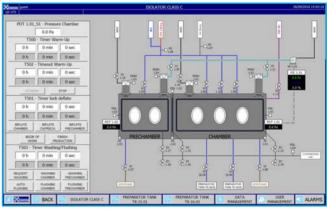
Hardware Specification

ingressi digitali

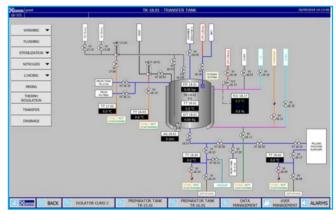
Automation System



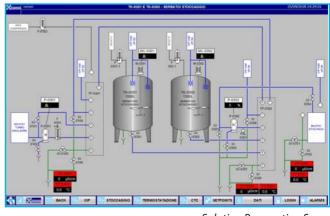




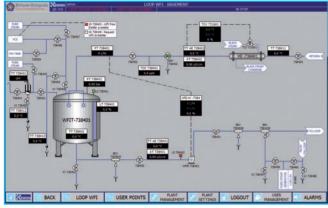
Isolator



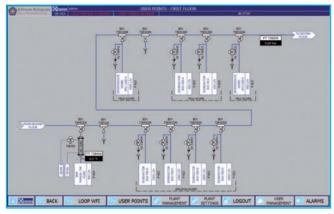
Trasfert Tank



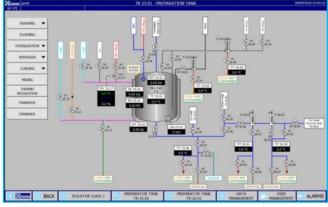
Solution Preparation Syn



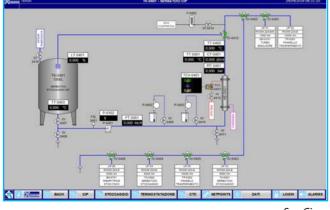
Loop WFI



Loop WFI - Distribution



Preparation Tank



Syn Cip



Validation Documents

Users safety, product quality and data integrity are fundamental values for REMOIN. Therefore, in the validation protocol supplied to the final customer, are included the Functional and Design Specification of the machine, as well as all the necessary test sheets in order to perform the tests during FAT and SAT. The validation documents issued by REMOIN consist of:

Standard documents:

Technical folder with:

- P&ID
- Layout
- Isometrics (piping & welding)
- Material certificates in contact with the product
- Boroscopies
- Welding specifications and procedures
- Welding reports
- Pneumatic P&ID
- Calculations
- Components list
- Instruments list
- Valves list
- Wiring diagrams and electrical list
- Instruments calibration certificates
- Operation manuals for components and instruments
- Hydraulic test reports
- Pickling and passivation reports
- PED certificates
- Operation manual

Documents provided upon request:

- Design Qualification protocol (DQ)
- Factory Acceptance Test protocol (FAT)
- Site Acceptance Test protocol (SAT)
- Installation Qualification protocol (IQ)
- Operation Qualification protocol (OQ)
- Performance Qualification Protocol (PQ)
- GAMP documentation

Factory acceptance test & Site acceptance test

In Order to verify the fuctionalities of our plants, we carry out the following activities:

Factory Acceptance Test

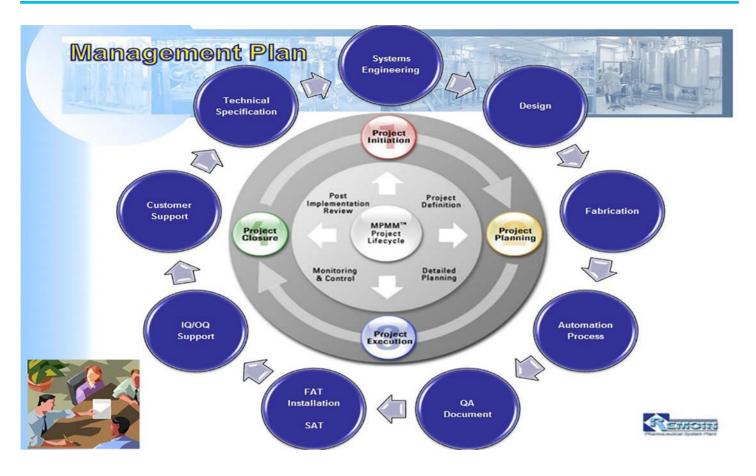
Test of the system at REMOIN premises: many tests are performed in REMOIN factory before delivering the plant to customer. These tests aim to show that the equipment works adequately and that it can be installed and tested onsite. The purpose is also to test the control panel of the plants, to carry out alarm tests and to check the plant performances. During FAT a complete check of the documentantion provided together with the plant is performed as well as the quality and the conformity of the whole plant and of each components.

Site Acceptance Test

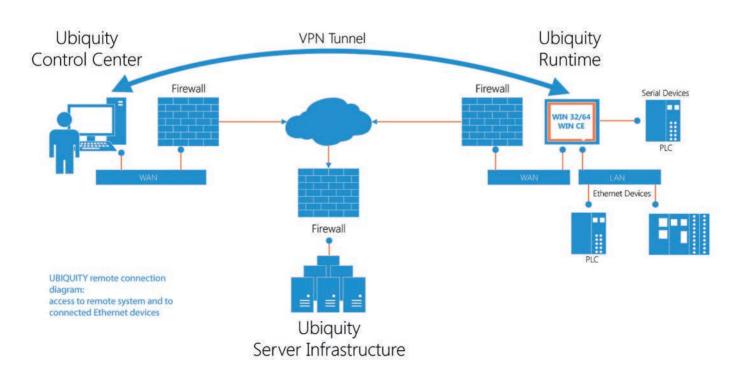
Test of the equipment at the final user: these tests want to show that the system works in its own defined operative location and that it interacts properly with other systems and devices. During SAT REMOIN technician inserts in the control panel all the necessary set points for the proper fuctioning of the plant according to the characteristics of customer's site. He carries out all the tests alredy performed during FAT and he certifies the conformity



Management Plan



Remote Assistance



REVERSE OSMOSISMULTI EFFECT DISTILLERTHERMOCOMPRESSION DISTILLERImage: state sta

PURE STEAM GENERATOR

SANITARY TANKS

SANITARY PIPING 3A



SOLUTION PREPARATION



S.P. with ISOLATOR



SOLUTION PREPARATION



TURBO EMULSIFIERS



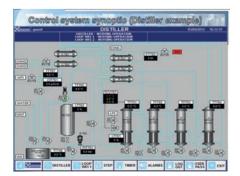
CLEAN IN PLACE SYSTEM



3D PROJECT



AUTOMATION SYSTEM





MANAGEMENT PLAN



REMOTE ASSISTANCE

