World Health Organization

Anexă

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Anexa 2

Achiziție sterilizator cu abur 200l

Lista cerințelor și specificațiilor

Sterilizator cu abur 200l					
NUME, CATEGORIA ȘI CODIFICARE					
Parametrii			**Specificație minimă așteptată**	**Caietul de sarcini propus (de completat de ofertant)**	**Documentul de referință / broșura / pagina în care informațiile furnizate pot fi verificate de către comisia de evaluare**
1	Nume generic	Sterilizator cu abur 200l, clasa B		**MODEL: VS4/2 E G2 Producător: Steelco S.p.a. Țara: Italia**	
CARACTERISTICI TEHNICE și CARACTERISTICI FIZICE					
2	CAPACITATE	Volumul camerei (convențional 200l), orizontal, cu încărcare frontală	min. 190l	DA 333 litres	pag. 2 din Data Sheet general VS G2
3	CADRU, CORP	Versiune cu uși duble, independente (de trecere)	da	DA este prezenta versiunea dubla	pag. 2 din Data Sheet general VS G2
		Cameră din oțel inoxidabil AISI 316L	da	DA camera din oțel inoxidabil AISI 316L	pag. 2 din Data Sheet general VS G2
		Cămașa din AISI 316L	da	DA AISI 316L	pag. 5 din Data Sheet general VS G2
		Față din oțel inoxidabil AISI 304L, capace laterale	da	DA AISI 304L sau 316Ti	pag. 2 , 5 din Data Sheet general VS G2
		Țevile, mecanismul de pompare de apă și fitingurile sunt fabricate din oțel inoxidabil 316L	da	DA AISI 316L	pag. 3 din Data Sheet general VS G2
		Ușă glisantă verticală complet automată	da	DA Ușă glisantă verticală automată motoriată	pag. 3 din Data Sheet general VS G2
		Etanșarea ușilor trebuie asigurată prin garnituri din silicon cu sistemul pneumatic și de vacuum	da	DA este prezenta	pag. 3 din Data Sheet general VS G2

		Ușa rămâne blocată până la sfârșitul procesului de sterilizare	da	DA este prezenta	pag. 7, 22 din User Manual Steelco VS G2 Series
		Ușa trebuie proiectată cu un sistem de siguranță pentru a preveni rănirea utilizatorului	da	DA este prezenta	
		Tip camera de sterilizare- dreptunghiulara	da	DA este prezenta	pag. 2 din Data Sheet general VS G2
		Egalizarea presiunii în camera de sterilizare este asigurată prin filtru HEPA	da	DA cu pori de 0,01 microni	pag. 2 din Data Sheet general VS G2
4	GENERATOR DE ABURI	Generator de abur incorporat. Sterilizatorul are un generator de abur incorporat complet automat, cu elemente electrice ca sursă de caldură.	da	DA este prezenta	pag. 3 din Data Sheet general VS G2 - *VS model type "I"*
		Sistem de monitorizare a nivelului de apă din generator	da	DA inclus	pag. 5 din Data Sheet general VS G2
		Încălzitoare interioare cu control separat și siguranță la scurtcircuit	da	DA este prezenta	
		Protecție la supraîncălzire. Această protecție previne supraîncălzirea generatorului de abur dacă protecția împotriva fierberii uscate nu funcționează.	da	DA este prezent	pag. 58, 59 din User Manual Steelco VS G2 Series - *sînt indicate erorile care demonstreaza prezența siguratie în cazul supraîncălzirei*
		Echipat cu pompa de vacuum pe baza de apa, integrată	da	DA este prezenta	
		Sistem de uscare: cu vacuum	da	DA este prezenta	
		Echipat cu pompa de apa de umplere a generatorului de abur, integrată	da	DA este prezenta	
		Răcitor/atenuator de abur (schimbător de căldură integrat) pentru sistemul de drenaj	da	DA este prezet	
		Camera generatorului din oțel inoxidabil AISI 316L	da	DA	pag. 2 din Data Sheet general VS G2
5	CICLU	Regimuri prestabilite de sterilizare	≥5 programe	DA 15 programe predifinite	pag. 1 din Data Sheet general VS G2
		Regimuri de sterilizare care pot fi programate de utilizator	≥10 programe	DA 50 programe pot di setate de utilizare	pag. 1 din Data Sheet general VS G2
		Setarea de către utilizator a regimului de sterilizare dorit	da	DA este prezent	pag. 4 din Data Sheet general VS G2
		Teste acceptate: test de vacuum (scurgere) și test Bowie-Dick	da	DA este preent	pag. 1 din Data Sheet general VS G2
		Control electronic: microprocesor	da	DA este prezent	pag. 2, 3, 6 din Data Sheet general VS G2
		Senzori de presiune independenți pentru generator, cămașă de protecție, cameră de sterilizare	min. 3 buc.	DA este prezent	
		Monitorizare digitală: temperatura camerei, presiunea camerei, presiunea generatorului, presiunea cămașa de protectie	da	Da este prezent si la fel se printeaza rezultatul.	pag. 28 din User Manual Steelco VS G2 Series

		Afișarea graficului de sterilizare pe ecran	da	Da este prezent	pag. 33 din User Manual Steelco VS G2 Series
		Gama de temperatură: 121 -134 grade C	da	Da 121 si 134 grade C	pag. 4 din Data Sheet general VS G2
		La sfârșitul ciclului de sterilizare trebuie să imprime un raport pe hârtie (stocarea paralelă a datelor în memorie).	da	Da	pag. 28 din User Manual Steelco VS G2 Series
6	SIGURANȚĂ	Protecție împotriva temperaturii excesive	da	DA	
		Dispozitivul trebuie să fie echipat cu software, protecție electrică și mecanică de siguranță	da	DA	
		Alarme: temperatură scăzută, eșec ciclu de sterilizare	da	DA	
		Camera va menține o presiune de testare ≥5 bar, echipată cu o supapă de siguranță	da	DA, prezenta si valva de siguranta pina la 4 Bar	
		Manometre minim 2, presiunea și temperatura trebuie să fie pe panoul frontal,	da	DA tempertarua este inregistrta digital si poate fi monitorizata live.	pag. 2 din Data Sheet general VS G2
		Ușile trebuie să fie izolate termic pentru a preveni ca temperatura suprafeței să prezinte un potențial pericol pentru operatori	da	DA este prezent	
		Sistemele de filtrare asigură decontaminarea aerului la intrarea în camera de sterilizare	da	DA filtru de 0,01 micorni	
		Sistem de protecție la deschiderea ușii în caz de presiune în camera de sterilizare	da	DA nu ermite deschiderea pina valaorea nu ajunge la 0 bar	pag. 22 din User Manual Steelco VS G2 Series
		Ușile se blochează pentru a preveni deschiderea ambelor părți	da	DA conform standatului EN285	pag. 4 din Data Sheet general VS G2
		Sterilizatorul cu abur ar trebui să fie prevăzut cu sisteme de monitorizare independente și cu alarme audio și vizuale pentru a notifica operatorii cu privire la orice problemă care necesită atenție. Un buton de oprire de urgență de pe partea de încărcare a autoclavului poate fi utilizat pentru a opri în siguranță ciclul autoclavului. Întrerupătorul de siguranță trebuie sa permita izolarea tuturor surselor de alimentare cu energie electrică a generatorului de abur. Întrerupătorul de siguranță trebuie să poată fi blocat în poziția OPRIT.	da	DA este prezent	pag. 15, 30 din User Manual Steelco VS G2 Series. Pag. 5 din Data Sheet general VS G2
CARACTERISTICI ELECTRICE					
7	CARACTERISTICI ELECTRICE	380V, 50 Hz, 3 faze de bază, 220V, 50Hz	da	DA	pag. 8 din Data Sheet general VS G2
Caracteristici electronice					
8	Caracteristici electronice	Panouri cu ecran tactil multicolor de minim 5 inchi de pe ambele părți	da	DA 7 inchi	pag. 7 din Data Sheet
		Niveluri de acces la meniul de service prin parole/ coduri de acces. Toate parolele/codurile de acces vor fi puse la dispoziția personalului tehnic la momentul predării-primirii dispozitivului	da	DA	pag. 23 din User Manual Steelco VS G2 Series
		Test de diagnosticare intrare/ieșire ce permite verificarea fiecărei componente a sistemului separat	da	DA	pag. 37 din User Manual Steelco VS G2 Series
		Port USB	da	DA pentru service	

8	Caracteristici electronice	Posibilitatea de conectare la Internet	da	DA	pag. 7 din Data Sheet general VS G2
		Software/pagina WEB prin intermediul rețelei TCP/IP instalat pe un calculator al beneficiarului din cadrul instituției pentru monitorizare de la distanță a parametrilor de performanță (temperatură, presiune, vacuum) și monitorizarea a mesajelor de eroare	da	DA	pag. 7 din Data Sheet general VS G2
		Memorie internă pentru stocarea a minim 1.000 de cicluri	da	DA	
ACCESORII, CONSUMABILE, PIESE DE SCHIMB, ALTE COMPONENTE					
9	Accesorii/ piese de schimb	Kit de întreținere pentru doi ani (trebuie să includă tot ce este da, dar nu numai, garnituri de uși, filtre HEPA)	da, 2 ani	DA inclus conform service manual	
		Lubrificator pentru garnitura ușii minim 200gr	da	DA	
		Set sau kit de testare a durității apei (minim 100 de teste)	da	DA	
		Imprimantă de date integrată (hârtia utilizată pe imprimantă trebuie să aibă dimensiuni universale utilizate în alte unități)	da	DA	
		Suport de încărcare, cu 4 nivele de stocare, adaptat pentru trecere în sterilizator, fabricat din inox	min.1 suport	DA inclus	
		Hârtie de imprimantă	min. 10 buc.	DA	
		Capcană de aburi (steam trap), cu instalare	da	DA	
		Sistem de încărcare (cărucior/troleu) adaptat pentru dimensiunea sterilizatorului cu abur oferit, oțel inoxidabil	min. 2 cărucioare	DA	
		Compresor de aer (fara ulei)	da	DA inclus	
INSTRUIRE, INSTALARE SI UTILIZARE					
10	Transport	Furnizorul trebuie să includă transportul până la unitatea medicală finală	da	DA	
11	Instalare	Furnizorul trebuie să efectueze complet verificările de instalare, siguranță și funcționare înainte de predare. Toate operațiunile trebuie să aibă un raport de conformitate. Trebuie asigurată instruirea utilizatorilor și a tehnicienilor.	da	DA	
		Supape de presiune pentru apă și pompe de evacuare a apei în canalizare, dacă este cazul	da	DA	
		Traseul de electricitate și canalizare a punctelor de racordare la sterilizatoare, va fi asigurat de beneficiar (confom recomandărilor producătorului)	va fi asigurat de beneficiar	DA	
GARANȚIE ȘI ÎNTREȚINERE					
12	Garanție și deservire completă (inclusiv piese de schimb)	minim 24 de luni	da	DA	
DOCUMENTAȚIE					
13	Cerințe de documentare	Toate documentele justificative, manualele de operare, de service trebuie prezentate în limba de stat sau în limba engleză. Manualul de utilizare/Instructiunile de utilizare trebuie prezentate în limba engleză și în limba de stat.	da	DA	
SIGURANȚĂ ȘI STANDARDE					

14	Standarde pentru producător	toate certificatele valabile enumerate mai jos: 1. Certificat de conofmritate CE conform directivei 93/42 EEC sau a Regulamentului 745 2. Declarația de conformitate CE conform directivei 93/42 EEC sau a Regulamentului 745 3. ISO 13485 și sau 9001 4. EN 285 5. IEC 61010- Cerințe de siguranță pentru sterilizatoarele utilizate pentru tratarea materialelor medicale	toate certificatele trebuie prezentate în copii cu ștampila de confirmare	DA	pag. 1 din Data Sheet general VS G2 *sînt declarate în documentele confirmativeiar o parte sît atașate la prezenta anexa.*

VS G2 series
medium capacity steam sterilizers

Steelco Steam Sterilizers VS G2 series are designed for the sterilization of heat-resistant medical devices such as surgical instruments plastic and rubber goods, porous loads, etc., used in Hospitals and Clinics.

These units are equipped with a 121°C and 134°C conditioning cycles as well as Warm-Up, Steam Penetration test (e.g. Bowie-Dick) and Leak test cycles.

The sterilizers are designed and manufactured in Italy, according to the standards listed below.

DESCRIPTION

Steelco Steam Sterilizers type VS G2 are equipped with a PLC digital microprocessor with a color touch screen HMI and an independent recording system.

Other features include:

- 65 programs, 15 pre-defined and other 50 that can be set according to the customer needs.
- Automatic vertical sliding doors, in single or double-door configuration.
- Door open/close standard settings conform current standards i.e. EN285
- 5 standard chamber sizes with a volume from 322 to 966 liters.

STANDARDS

Steelco Steam Sterilizers type VS G2 meet the applicable requirements of the following standards:

European Directive for Medical Devices:

- 93/42/EEC and its revised versions

Pressure Equipment Directive:

- 2014/68/EU

Technical norms and standards:

- EN 285
- EN ISO 14971
- EN ISO 17665-1
- IEC EN 61010-1
- IEC EN 61010-2-040
- IEC EN 62366
- IEC EN 61326-1
- IEC EN 62304

Steelco S.p.a. - VIA BALEGANTE, 27 – 31039 RIESE PIO X (TV)
Tel. 0039 0423 7561 www.steelcogroup.com e-mail: info@steelcogroup.com
Capitale sociale Euro 3.000.000,00 i.v. C.F., P.IVA e Numero Registro Imprese di Treviso: 04311220265 REA TV 339832

Type	Chamber dimensions (mm)			Useful Capacity (litres)	Overall dimensions (mm)		
	Width	Height	Lenght		Width	Height	Lenght (*)
single door models							
VS 4/1 G2	670	700	686	322	950	2400	992
VS 6/1 G2	670	700	986	462	950	2400	1292
VS 8/1 G2	670	700	1286	603	950	2400	1592
VS 10/1 G2	670	700	1760	810	950	2400	2042
VS 12/1 G2	670	700	2060	925	950	2400	2342
double door models							
VS 4/2 G2	670	700	710	333	950	2400	992
VS 6/2 G2	670	700	1010	474	950	2400	1292
VS 8/2 G2	670	700	1310	614	950	2400	1592
VS 10/2 G2	670	700	1760	825	950	2400	2042
VS 12/2 G2	670	700	2060	966	950	2400	2342

Loading height: 850 mm above finished floor.

BASIC MACHINE CONFIGURATION

- Steam autoclave type VS G2, single or double door, floor mounted
- Vertical sliding door
- Technical area on the top and bottom of the chamber
- Pressure vessel PED marked
- Pressure relief valves PED marked
- Full jacket chamber
- Rectangular chamber
- Execution of machine in compliance to EN 285 and HTM 2010
- Frame and external panels made of AISI 304 stainless steel
- Chamber made of AISI 316L stainless steel
- Chamber fine satin finishing (2 um)
- Degreasing and passivation of the chamber and the process pipes
- Chamber rails for the manual or automatic loading of carts and baskets
- Application of separated water supply feeding lines for steam generator and vacuum pump
- Vacuum pump single or double stage type
- Chamber piping with tri-clamp fittings
- NCG sensor ready: Independent measuring device to determine the steam sterilization conditions in the chamber during every process.
- PLC control system with an independent recording system
- Electrical power supply (400V, 50Hz)
- #2 standard cycles for medical devices (121°C and 134°C)
- #3 basic test cycles
- Pipe work for the exhaust of pressure safety valves (tbd. If below or above)
- Steam or compressed air (optional) pressurized silicone door seals
- Vacuum breaker filter remove solid and biological particles down to 0.01 micron (filter can be sterilized)
- Interface to traceability system
- Thermal printer
- Utility connections
- Connections for external pressure and temperature probes
- Prepared for independent NCG sensor
- Manometers on loading and unloading side conform EN 285

Steelco S.p.a. - VIA BALEGANTE, 27 – 31039 RIESE PIO X (TV)
Tel. 0039 0423 7561 www.steelcogroup.com e-mail: info@steelcogroup.com
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STEAM FEEDING SYSTEMS

The steam sterilizer can be configured:

- With the connection for external clean steam supply. **(VS model type "V").**
- With an **integrated electrically heated steam generator**. (**VS model type "E"**).
- With an **integrated indirect steam/steam generator** connected to an external industrial steam supply. (**VS model type "I"**).
- With an **integrated steam generator with mixed heating (**electrical and steam/steam fed by an external industrial steam supply). (**VS model type "E/I"**).
- Combining **steam generators and external steam sources.** (**VS models type "E/V", "I/V"….**).

Timer/cycle controlled blow down to grant proper and clean steam supply for all the versions of steam generators.

FEATURES

PLC based control system: equipped with a 7" color touch-screen HMI. The color touch screen display is installed on the loading-side of the sterilizer at eye level allowing easy monitoring of all the cycles. During the cycle the display shows the estimated remaining time to the end of the cycle. An additional 7" HMI panel is installed on the unloading side on the double-door versions. It allows the operator to see the status of the sterilizer.

Pressure gauges

Pressure gauges are installed on the control/loading side of the sterilizer to monitor the steam pressure in the sterilization chamber, in the jacket and in the steam feeding line or in the steam generator. In case of double door sterilizer, on the unloading side the pressure indicators of the sterilization chamber gauge and the jacket gauge are replicated.

Sterilization chamber

rectangular and made of AISI 316L, Ra < 2 µm finish stainless steel (6 mm thickness). The chamber is fully jacketed (6 mm thickness), easy to clean and self-draining. Clean steam process pipes are made of stainless-steel.

The external insulation of the chamber is realized with non-toxic fiber, (20 mm thickness). The covering reduces the heat loss and the noise level and, thanks to its fabric coat, can be removed for easy maintenance operations.

Steam generator

Cylindric shaped welded steam generator and made of AISI 316L, stainless steel (4 mm thickness). The external insulation of the steam generator is realized with non-toxic fiber, (20 mm thickness).

Service access panels

Piping, valves, electrical components and wiring are accessible through frontal service access panels located on top and below the chamber of the machine. The machine can be installed next to a wall or next to another sterilizer, access for service is provided by opening the front technical door access panel (and the rear one in the double-door units).

Door system

The vertical sliding doors are made of stainless steel AISI 316L (12 mm thickness). The external insulation of the door is realized with non-toxic fiber, (20 mm thickness).

The vertical movement is activated through a toothed belt motorized system to guarantee silence and precision during the phases of opening and closing.

An innovative and high sensibility safety bumper guarantees the safety of the operator.

The perimetral silicone seal is inflated by hot steam or compressed air (optional) and ensures the tightness of the chamber.

External paneling

The autoclave is made with paneling in hinged elements that can be opened with a key lock both on the loading side and on the unloading side if with double doors.

Paneling is made of AISI 304 stainless steel sheet with scotch brite finish. The door paneling integrates the control panel with display and the technical control and safety instrumentation of the device.

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SAFETY FEATURES

Steelco Steam Sterilizers type VS are equipped with a **Safety Lock** to avoid the operator to start a program execution before the door is fully closed. The door is mechanically locked during the whole cycle and cannot be opened until cycle completion and pressure and temperature in the chamber are normalized. The machine is equipped with piezoresistive transducers, over-temperature devices, devices against opening the door in the presence of pressure in the chamber, a device that prevents the simultaneous opening of the door, short-circuit and overheating protections. An emergency push button is located in front panel of the autoclave (and the rear one in the double-door units). A main power ON/OFF switch, is located on the electrical box.

PROCESS CYCLES

Process cycles according to EN 285 are factory programmed and available for the operator selection in the control panel.

Cycle configuration:

sterilizers are factory programmed with the following cycles: 134°C and 121°.

Temperature inside the chamber is uniform in every part, and the temperature deviation is less than 0,5°C.

Sterilization temperature:	134°C
- Sterilization time:	5 Minutes
- Drying time:	20 Minutes
Or:	
Sterilization temperature:	121°C
- Sterilization time:	20 Minutes
- Drying time:	20 Minutes

Prion cycle (activated on request on site by Steelco service technician):
the purpose of this cycle is to comply with local legislation when processing presumably prion contaminated instruments. Process needs to be validated on site under customer responsibility.

- Sterilization temperature:	134°C
- Sterilization time:	18 Minutes
- Drying time:	20 Minutes

CYCLE DESCRIPTION

ADVISORY NOTE: STEELCO Steam Sterilizers VS series are intended to perform the sterilization of reusable medical devices only.

Once a program is started, the sterilizer automatically processes the load through a predefined combination of the following standard phases. All cycles cannot be modified by the operator to include the following typical treatments:

- Conditioning – This phase is executed to reach the optimal conditions needed for a sterilization cycle as well as a Test cycle. A series of pulses of vacuum and pressure with steam is generated inside the chamber. The last steam injection will bring the chamber pressure and temperature at the sterilization value.
- Sterilization – The temperature and the pressure of the chamber are kept steady for the needed sterilization time.
- Drying – The fractional vacuum is realized continuously into the chamber for a specified time, at the end, the atmospheric pressure is re-established.

Additional cycles can be customized.

TEST CYCLES

Vacuum Leak Test: this cycle is used to verify the vacuum integrity of the sterilizer. While running this cycle, the sterilizer chamber must be empty. This cycle is factory programmed following EN 285 and cannot be modified.

Steam Penetration Test: this cycle is used to verify the effectiveness of the steam penetration and air removal for the sterilizers provided with a vacuum pump.

- Sterilization temperature:	134°C
- Sterilization time:	3.5 Minutes
- Drying time	5 Minutes

Hollow load Test: the purpose of this test is to check the steam penetration when processing hollow instruments. This test is performed with a testing device in compliance with the current technical regulation and is requested for all the autoclaves intended for the sterilization of hollow instruments.

- Sterilization temperature:	134°C
- Sterilization time:	3.5 Minutes
- Drying time:	5 Minutes

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OPTIONS

- Visual water level control for steam generators for the following versions:
  E,I,EV,IV and EI.
  In certain countries it could be mandatory (due to local pressure vessel directives) to provide this option.
- Remote steam generator (technical feasibility to be verified in relation to the design of the installation site).
- ECO 2 Water cooling system of the operation of the vacuum pump (heat exchanger fed by external chilled water source).
- Jacket made of AISI 316L stainless steel
- Chamber electro polishing
- Chamber, doors and jacket made of AISI 316Ti stainless steel
- Chamber equipped with 2 extractable shelves. Available only for VS 4 G2 and VS 6 G2.
- Performance vacuum pump (only for 10 12 STU capacity)
- Remote vacuum pump (technical feasibility to be verified in relation to the design of the installation site).
- Pressure reduction valve for external clean steam source
- Pressure reduction valve for external industrial steam source
- ***4D IR sensor:*** This unique sensor is available on all sterilizers starting from 4 STU. It measures the density of the steam and is applicable on all Steelco standard sterilization programs and as a steam penetration test following ISO EN 11140-4. The major benefit is that it can replace the daily Bowie and Dick Test as a steam penetration test as well. It works by Infra-Red light with a specific wavelength that permits that only saturated steam with the right density can absorb the IR- light. Thus, saturated steam is ensured. In case that the IR light wouldn´t be absorbed an on-screen alert would be visible, and the cycle has failed.
- Set up for future 4D IR sensor
- Application of thermo couple fitting (up to 16 thermo couples)
- Pipe work for testing steam quality According to EN285
- NCG sensor: Independent measuring device to determine the steam sterilization conditions in the chamber during every process.
- Degassing device: built-in water tank in on top of the machines. Further advantage to keep the NCG concentration lower than 3,5%Vol. conform EN285 and for water feeding in case of emergency.
- Air detector system through check valves: automatic version. It allows the detection of the air in the chamber during the conditioning phase (before the sterilizing). Based on the measuring of the temperature in a special pipe. An additional alarm triggers if the temperature is less than the expected. According to HTM 2010.
- 7” HMI remoted on the conveyor.
- 10” HMI on loading and/or unloading side
- AutoStart functionality and autorun of a predefined cycle sequence i.e. warm up, BD-Test (by 4D sensor)
- Acoustic signal for -end cycle- and alarms
- Application of a UPS (Uninterruptible Power Supply) for device control system
- Free contacts (for critical alarms) these contacts (also called "dry contacts") are physically operated with the main device, but not electrically connected to it. Used in case of alarms or for the working cycle.
- Barcode reader system identification (hand scanner) for the recognition of the sterilizer load and automatic selection of the cycle
- Technical area's gauges set + door closing warning buzzer for C14 compliance - according to HTM 2010 for Australia, Canada, Ireland, Norway, UK.
- Set up for independent recorder, temperature and pressure probes for C14 compliance - according to HTM 2010 for Australia, Canada, Ireland, Norway, UK.
- Independent recorder with temperature and pressure probes and display for C14 compliance - according to HTM 2010 for Australia, Canada, Ireland, Norway, UK.
- Side panels for free standing installation
- Back paneling for single door versions
- Disassembling option for shipment and installation.
- Floor pit to collect leakage water and to avoid inundation thus major damages in the CSSD area.
- Application of seismic anchoring
- Set of spare parts for two years of activity PM Kits

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ACCESSORIES

Air Compressor

It produces the compressed air to feed the Sterilizer. In case compressed air is not available.

Water softener

It reduces the hardness of the water to be supplied to the vacuum pump.

Loading carts and transport trolleys

Loading carts (made of AISI 304 stainless steel) are available with one or two shelves and with half or full chamber depth

Transport trolleys (made of AISI 304 stainless steel) with fixed or adjustable height

Easy load system in Stainless steel AISI 304L

This allows to load or unload the sterilizers without using loading shelves. This system is only applicable to stackable baskets or containers.

Major advantages: No return hatch for loading racks needed furthermore no loading racks needed, This system is available in 2 different version:

1. Basket feeder incl. transport trolley for direct connection to the chamber rails.
2. Transport trolleys with lateral wheels for connection to load or unload the conveyor belts.

Both systems are available with fixed or height adjustable loading trolleys.

Conveyor belts for loading and unloading in stainless steel AISI304L

The conveyor belts are available for all machines starting from 4 up to 12 STU for loading and unloading. Also a possibility for loading and unloading of 2 racks i.e. 2x6STU in VS12/2 with vertical doors is given.

Connection to ATS System made of stainless steel AISI 304L

Starting from 6 STU up to 12 STU the connection to the ATS system is applicable. This is a space saving solution in a CSSD due that just 1 conveyor belt is installed therefore this solution is mostly applicable from 3 sterilizers in line upwards.

CONTROL SYSTEM

Design Features

The control system consists of an industrial PLC with a 7” (10” option) color touch-screen panel with Input/ Output modules and a printer on the loading side.

The system controls the sterilization process and records data related to every cycle.

Informational display 7” (10” option) on the unloading side

PLC based control features:

- The control system includes #2 pre-programmed and validated working sterilizing cycles, #3 test/service cycles and #50 additional cycles to meet additional customer requirements.
- The parameters of each cycle are programmed to run through each phase automatically.
- Users access control. The access to the control system is granted with 4 levels of restrictions. In order:

  1) **Default** can access the normal operation of the machine: switch on/off, run cycles, reset non critical alarms, open the doors.

  2) **Supervisor**: as Default + set date and time, reset critical alarms, printer setup.

  3) **Cycle editor**: as Supervisor + edit the cycles parameters.

  4) **STEELCO Service**: Complete control. The last three levels require the operator login with username and password. Username and passwords are managed by users with STEELCO service level.
- Simplified user interface prompt the operator for the possible operations also if an alarm occurs. “Cycle selection and execution”, “door open and close”, “reset alarm”, “Abort the cycle” are executed simply touching the icons on the screen.
- Built-in service screens permit the maintenance people to gain access to the function of calibration and of verification of components operation.
- Built-in service screens permit the supervisors to easily setup the machine.
- All the operations on the touch screen are logged by the control system in a file for service/maintenance and information use.
- During the cycle the temperature and pressure are recorded at 1 sec. intervals time in compliance to EN285.

Steelco S.p.a. - VIA BALEGANTE, 27 – 31039 RIESE PIO X (TV)

Tel. 0039 0423 7561 www.steelcogroup.com e-mail: info@steelcogroup.com

Capitale sociale Euro 3.000.000,00 i.v. C.F., P.IVA e Numero Registro Imprese di Treviso: 04311220265 REA TV 339832

- Printout of the cycle report. At the end of the cycle the impact printer prints-out a report of the cycle in compliance to EN285. It also prints out the time at machine switching on and switching off.
- ***4DIR sensor*** Complete monitoring of all relevant data incl. printout at the end of the cycle.

Technical Data

The control system includes a **Ethernet port** for the connection to a tracking system or a network.

Steelco Data live

This system permits to collect all relevant data and the connection via network to an external tracking system

System interface, print reports and manuals are available in multiple languages: English, German, Spanish, French, Italian.

Other languages may be available on request.

The 2 Resistive Temperature Devices (RTD) PT1000 installed in the sterilizer allow the control system to check and register the temperatures. The pressure sensors are converted into a 4-20 mA signal. These electric signals are read by the control system by means of the Input/output devices and provide accurate control and readouts of the temperatures and pressures throughout the entire sterilization cycle. The HMI and the PLC software together allow Individual calibrations of all temperature and pressure sensors. This operation must be performed by a trained service technician.

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STEELCO concerning annual maintenance programs.

Under the terms of these programs, preventive maintenance, adjustments and replacement of worn parts are provided on a scheduled basis to help ensure optimal equipment performance and help minimize untimely or costly schedule interruptions.

STEELCO maintains a worldwide staff of well-equipped, factory-trained technicians to provide these services, as well as on-site installation, training and expert repair services. Contact STEELCO for details.

NOTES

1. Customer must ensure that sterilizer stands on a leveled floor suitable to sustain the load of the device. Pipe sizes shown indicate terminal outlets only. Building service lines, which are not provided by STEELCO, must supply the specified pressures and flow rates.
For “special” installations (e.g. equipment installed on existing equipment compartment, recessed or placed beside other equipment) all internal parts shall be adequately protected to prevent direct accessibility to them by non-qualified personnel. Check the device installation drawing and contact STEELCO for further installation clarification.
2. STEELCO recommends that cut-off valves and vacuum breakers (not provided) are installed on service lines, and that disconnect switches (with lockout in OFF position; not provided as standard) are installed in electric supply lines near the equipment.
3. In the design of the installation environment heat dispersion must be considered. Ventilation of the service area must be sized according this dispersion.
4. STEELCO recommends illumination of the service area (if applicable) along with the provision of a convenience outlet for maintenance.

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Required utilities

For connection details please refer to installation drawing of the selected model/version.

Electrical power supply
Standard configuration for European power supply voltage 400V 50 Hz 3~ + PE. No neutral is required.

Cold water (according EN 285)

Reversed Osmotic or demineralized water (according EN 285 requirements)

Saturated clean steam (according EN 285)
(if required by the specific configuration)

Industrial steam
(if required by the specific configuration)

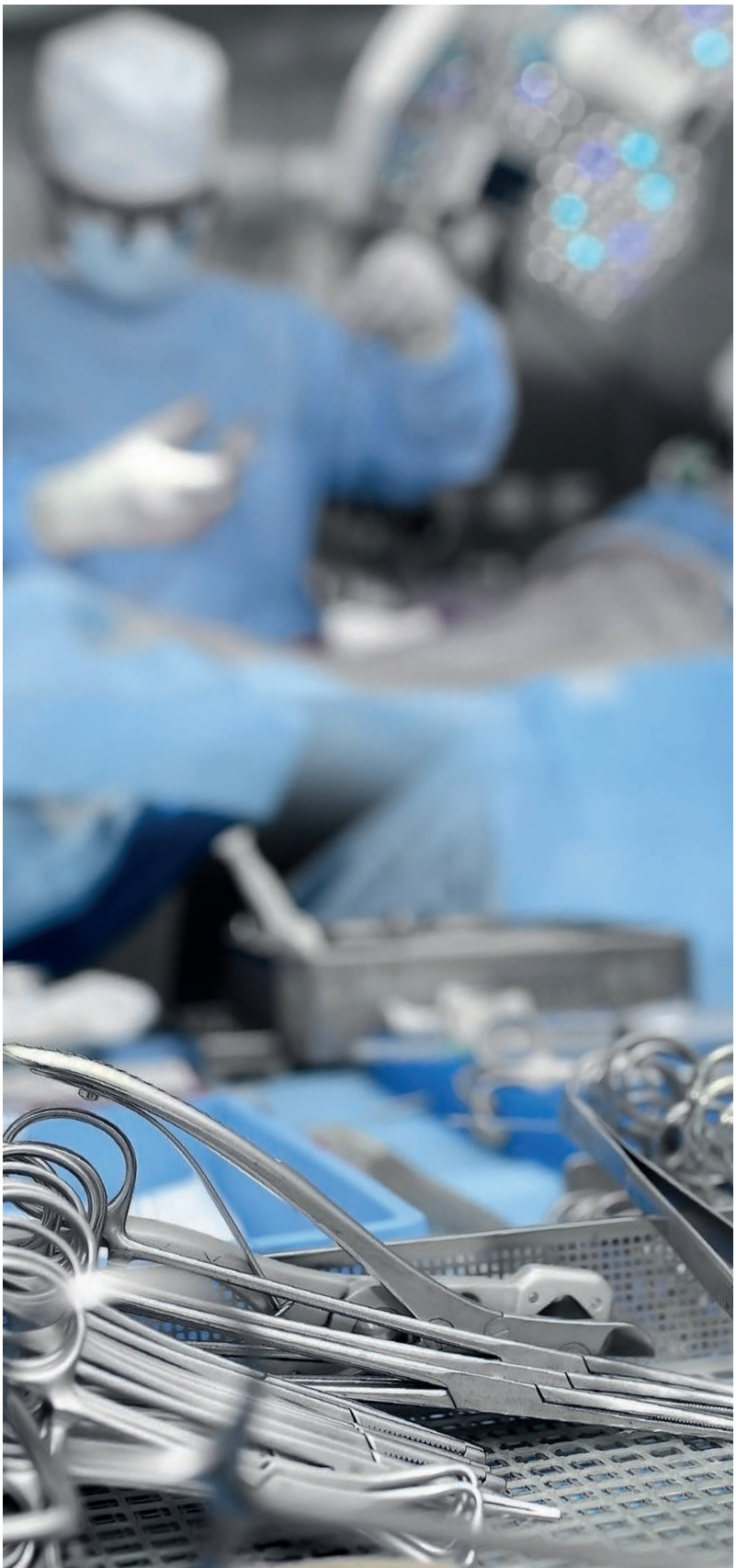
Compressed air

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS
For further information please contact:

STEELCO Spa
Via Balegante 27
31030 Treviso
ITALY
Phone +39 0423 7561
www.steelcospa.com
steelco@steelcospa.com

SteelcoData Live & Pro

sterilization management & traceability systems



Miele Group Member

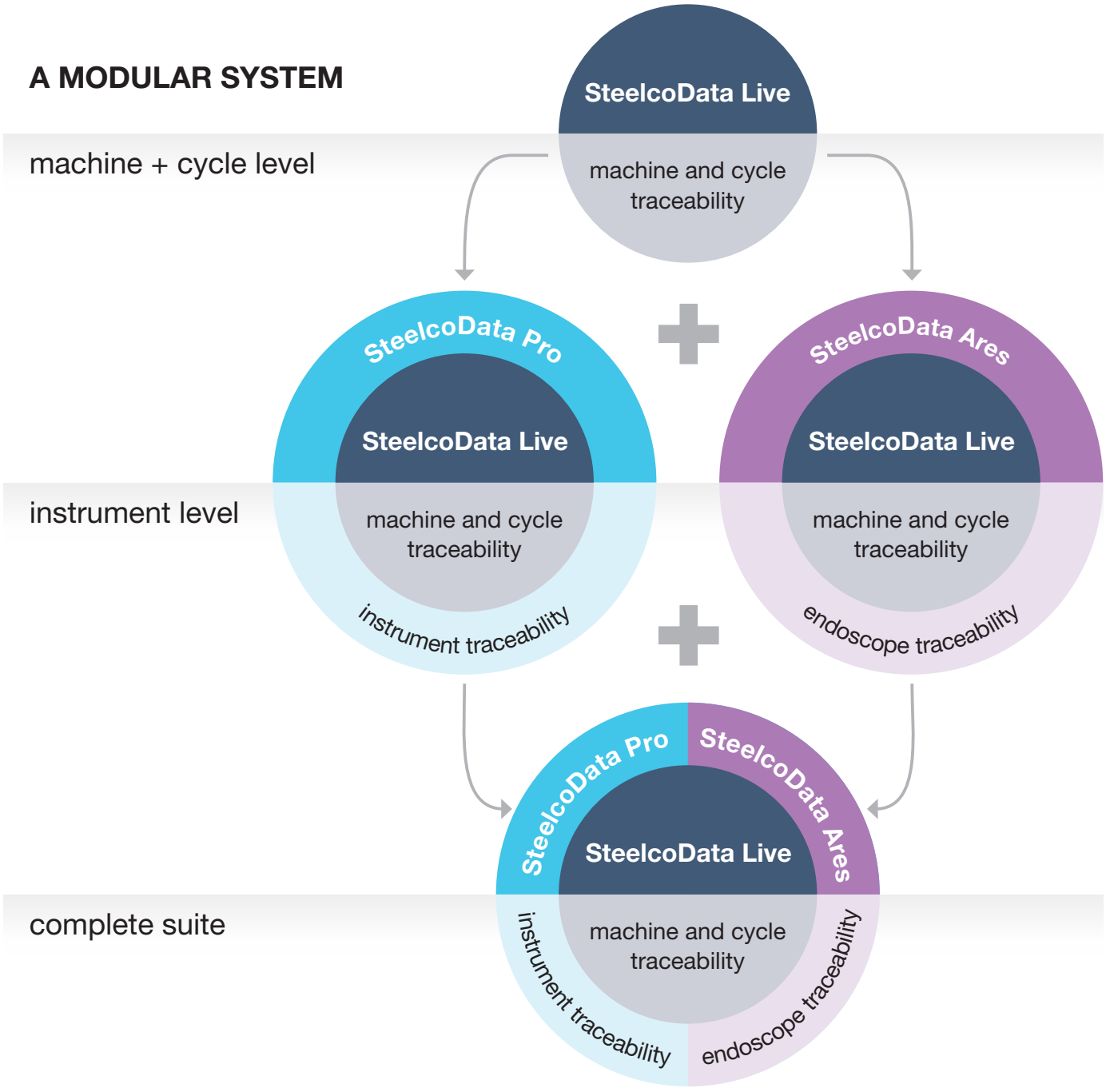
SteelcoData Live & Pro

sterilization management & traceability systems

Steelco helps you to ensure you have the right instruments in the right place at the right time, reprocessed to the correct standard in the minimum amount of time and the lowest cost on a consistent basis.

Steelco has developed a suite of different tailor-made solutions to ensure you have the information you need on the performance of your CSSD equipment, the cycles they are running as well as full traceability of surgical sets and instruments.

A MODULAR SYSTEM



THE BENEFITS OF A FULLY INTEGRATED SUITE

- Can start with a single workstation and configurable to any size of facility.
- Integrate with other client software programs such as patient scheduling, logistics, accounts, databases as well as remote service monitoring, etc…
- Be used at multiple locations within the healthcare network.
- Be able to be accessed by staff anywhere there is an internet connection and a Windows or iOS base computer/ tablet or other intelligent device.
- Provide customised reports and send alerts as needed.
- Is intuitive to use with excellent application and technical support available up to 24/7 in a multitiude of languages depending on contract.

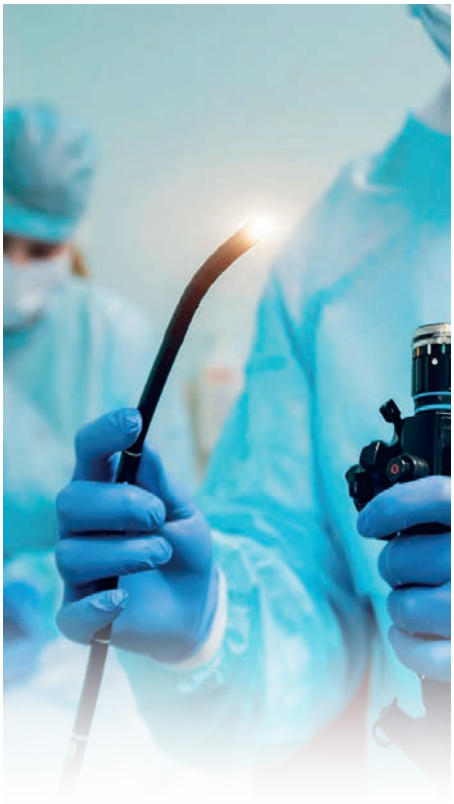
SteelcoData Live

Allows you to see in real time as well as historic records of machine performance, cycles performed, any alarms as well as utility consumption.

SteelcoData Pro

Provides you the possibility to track sets as well as individual instruments from their use in the OR through each stage of reprocessing, transportation and storage until they are ready to be used in ORs again.

SteelcoData Ares



Enables you to track endoscope and their reprocessing from the patient trolley through each stage of endoscopes reprocessing, transportation and storage until they are ready to be used on the next patient.

See dedicated brochure.

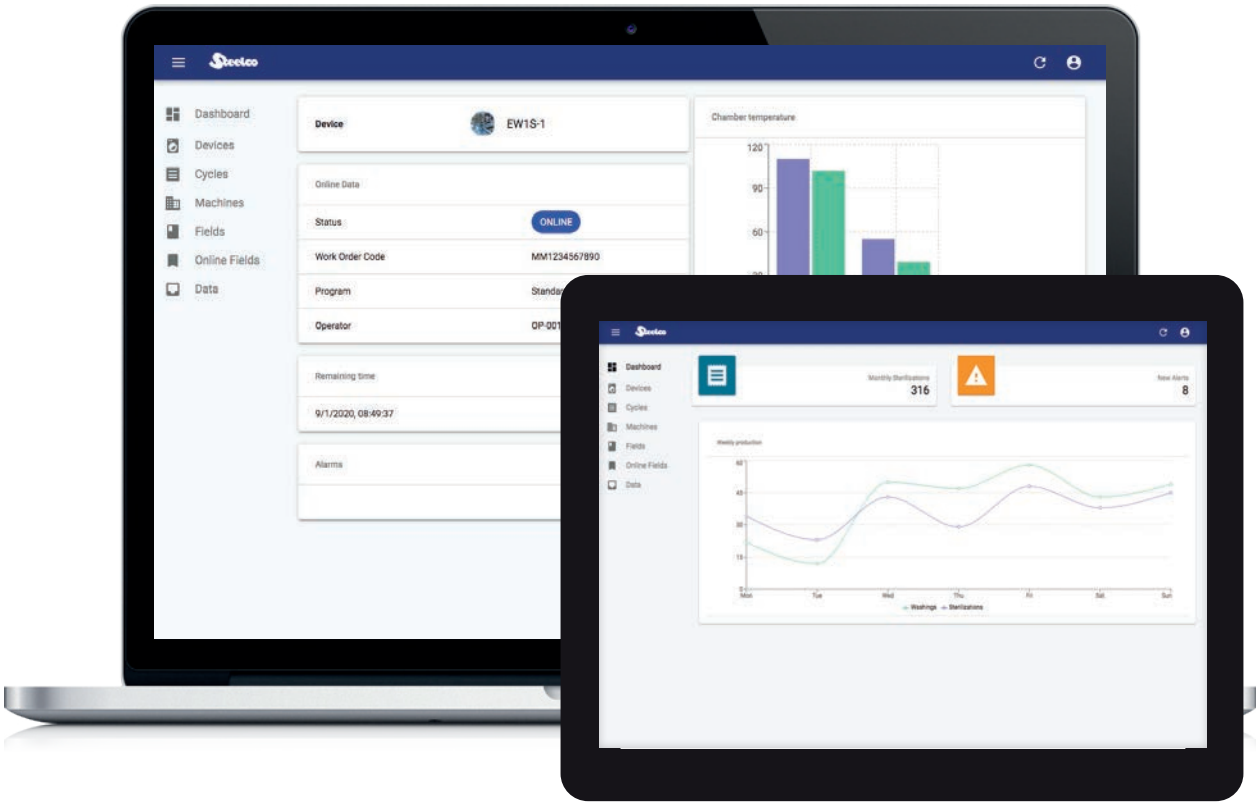
SteelcoData Live

machine and cycle traceability

SteelcoData Live

The software has been designed to accomplish data acquisition from Steelco devices. Information collected in real time are traced and efficiently visualized for device monitoring and data management.

SteelcoData Live is also the connection between Steelco machines and any software processing the data collected such as SteelcoData Pro and SteelcoData Ares.



KEY FEATURES

Steelco Data Live Software collects and records data from Steelco machines.

A user-friendly web interface shows real time machine statuses (video-wall or tablet wi-fi or workstation).

All the electronic stored data can be exported in different formats (.pdf, .xlsx), producing reports which can replace the paper tickets.

MAIN ADVANTAGES

WEB BASED – CLOUD READY
Users can log into the system through a standard web browser.

No client installation is required.

MODULAR
Starting with basic features, SteelcoData Live can be implemented in time with additional modules according to the specific needs of the customer.

ECO FRIENDLY
The collected data from the machine is stored in pdf reports which can replace paper tickets.

PARAMETERIZABLE
The system can be completely parameterized and configured using access policies that allow operators to display only information in their area of competence.

INTEGRATION
SteelcoData Live is designed to be integrated with the different equipments used in the CSSD and collection of their information (instrument washers, sterilizers, endoscope washers, drying cabinets) and with other software applications.

MULTI LANGUAGE
Available in English, German, Italian, French, Spanish, Russian and many other languages.

USER FRIENDLY
Guided procedures and simple user interface (touchscreen monitors).

MAIN COMPONENTS

DASHBOARD
The dashboard shows a graph with the number of washes and sterilizations happened in the current week.

DEVICES
It's possible to visualise a list of the machines in a CSSD, check their current statuses and look back at cycles. At any point the machine ID details can be updated or new machines can be added.

SteelcoData Pro

sterilization management & traceability system

SteelcoData Pro

The software has been designed to accomplish operational needs of central sterile service departments (CSSDs), to trace efficiently information and to provide CSSDs with an accurate monitoring tool that helps keeping high productivity standards.

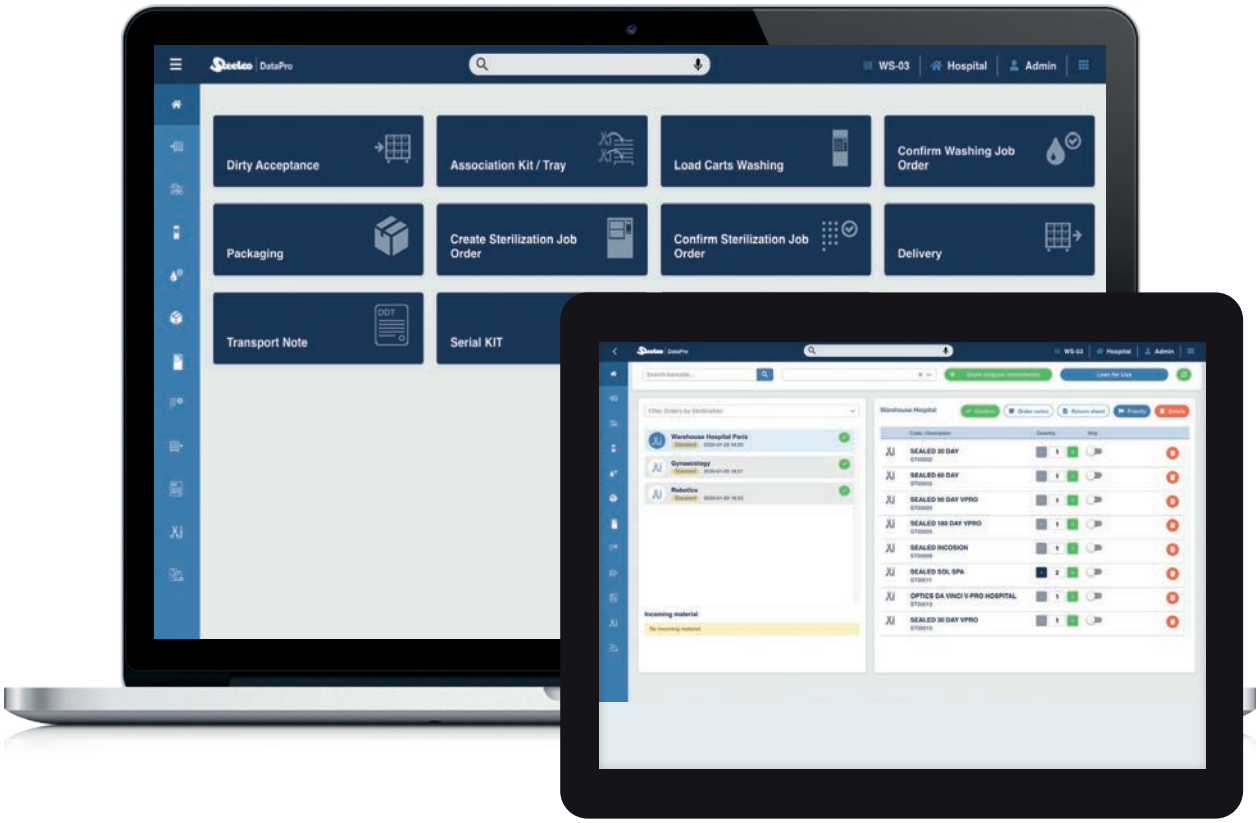
INTRODUCTION

SteelcoData Pro provides leading-edge technologies to manage information with the aim of improving daily activities in the CSSD. The system can efficiently monitor activities in every area of the CSSD so that sterile departments can progressively perfect their services and results.

Modularity is **SteelcoData Pro**'s main feature: the different areas of the CSSD are provided with different modules that cover all their different needs.

Modules can be easily activated or deactivated or configured according to customers' requirements and the types of activities. This modular architecture allows the system to be easily modified in future due to improvements and/or to different needs of CSSDs.

Recording information in the production and the shipment area, in the warehouse and tracking times between the different areas and in production allows **SteelcoData Pro** to define precisely production costs for cost centre.



Full traceability of procedures in all areas of the CSSD.

SYSTEM FEATURES

- results in line with hospital needs
- respect of high security standards required
- reliable information and data entirety
- traceability and backward traceability of user activities and material handling
- full coverage of activities in the CSSD
- real-time analysis of the CSSD
- efficiency improvement
- procedure automation avoiding unnecessary steps
- users and workstations can display only activities in their area of competence
- effective information sharing with customers

MAIN ADVANTAGES

WEB INTERFACE – CLOUD READY

Users can log into the system using a standard browser from any workstation within the corporate intranet or using the Internet if they are outside of the hospital.

No client installation required.

MODULAR

Starting with basic features, SteelcoData Pro can be implemented in time with additional modules according to the specific needs of the CSSD.

PARAMETERIZABLE

The system can be completely parameterized and configured by the company using access policies that allow operators to display only information in their area of competence.

INTEGRATION

Integration with the different equipments used in the CSSD and collection of their information (instrument washers, sterilizers), integration with administration and finance (customer contracts, customer masters, delivery notes, invoices) and warehouse systems (in CSSDs, hospitals)

USER FRIENDLY

Guided procedures and simple user interface (touchscreen monitors).

MULTI INPUT MODE

- TOUCH SCREEN
- VOCAL CONTROL
- BARCODE
- DATAMATRIX™
- RFID TAGS
- 3D SCANNER

MULTI LANGUAGE

Available in English, German, Italian, French, Spanish, Russian and many other languages.

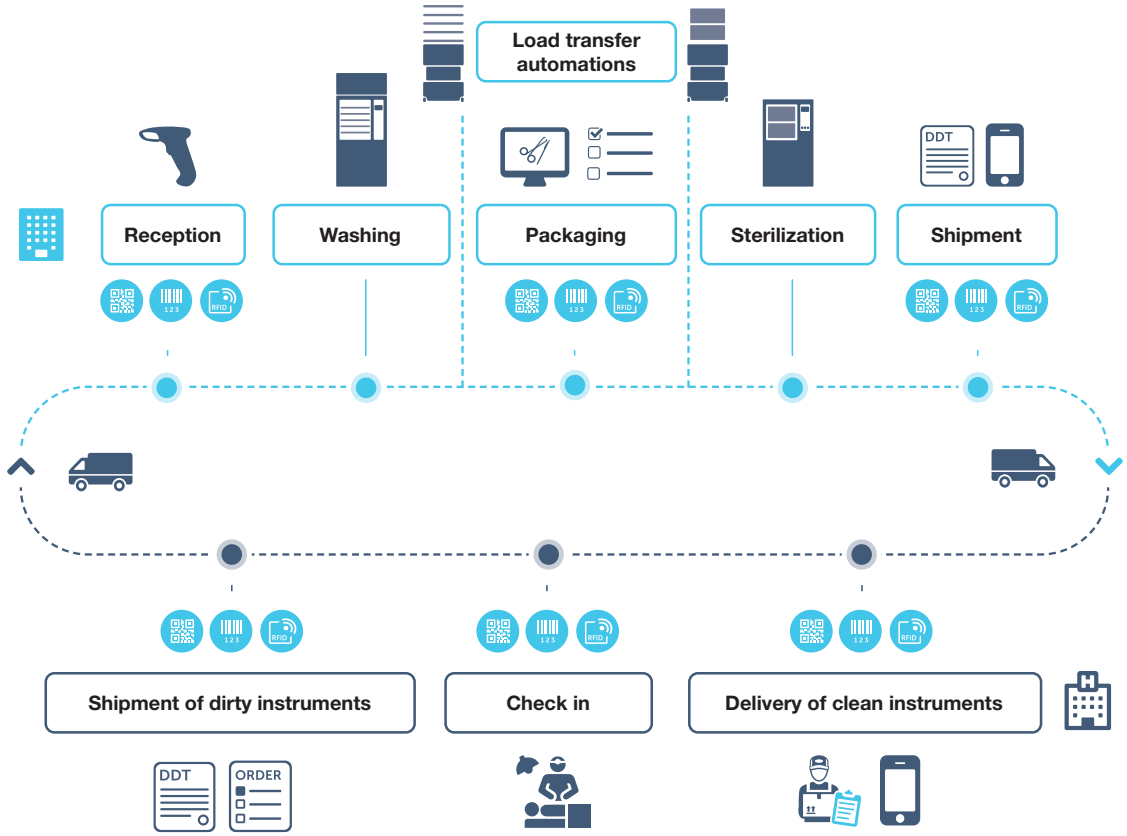
MULTI...

Multi customers and CSSD, Multi platform and multi database.

Pro

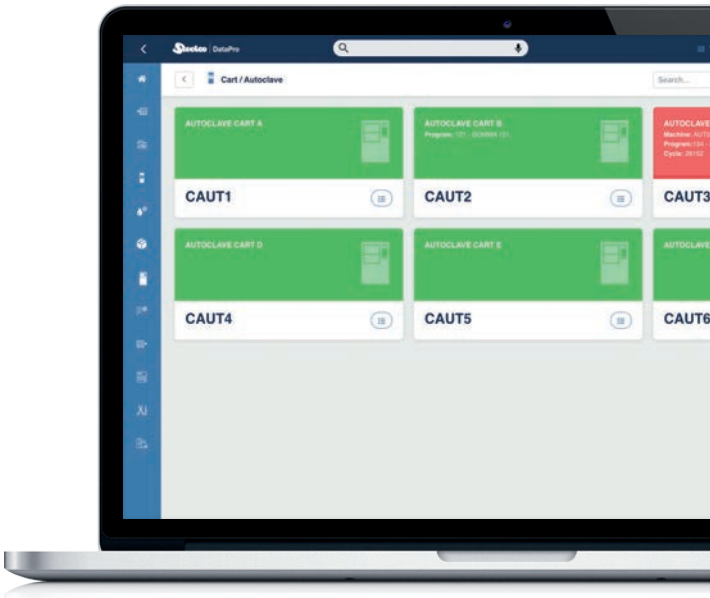
SURGICAL INSTRUMENTS MANAGEMENT WORKFLOW

SteelcoData Pro is a complete software application designed to trace surgical instruments in central sterile service departments (CSSDs). The software architecture is based on different check-points that every instrument/tray has to succeed in order to be processed by the CSSD and move to the next area/department.



When instruments move to the next area in the CSSD, the system checks they that previous step was successfully undertaken. Operators are acoustically advised if operations have been done correctly.

Surgical instruments to be sterilized can be codified using Datamatrix™, Barcodes, RFID tags, as identification system, including the use of 3D scanners, touch screen monitors and vocal control.



WORKFLOW

SteelcoData Pro workflow is based on the following steps:

1

RECEPTION

Identification of incoming instruments owned or rented instruments / loans for use and identification of special decontamination/washing methods needed to be performed as well as their priorities.

2

WASHING (including load transfer automations when present)

Every instrument/tray in the washing area is assigned to a specific container and an instrument washer, users can trace them at any time, getting information about their location and progress. Electronic collection of washing results and working procedures (washing program, procedure serial number).

3

PACKAGING (including load transfer automations when present)

Instrument packaging according to specifications defined for containers or surgical packs. Check of surgical instruments (both quantities than use/function) and management of potential non conformities. In this case instruments are sent to maintenance or they are sent back to the washing area. At this point the system prints a tag with traceability information and production lot.

4

STERILIZATION

Match trays and surgical packs with sterilizers to start sterilization procedures and print of the sterilization validation report. Management of contract work for special instruments that may be sterilized by third parties.

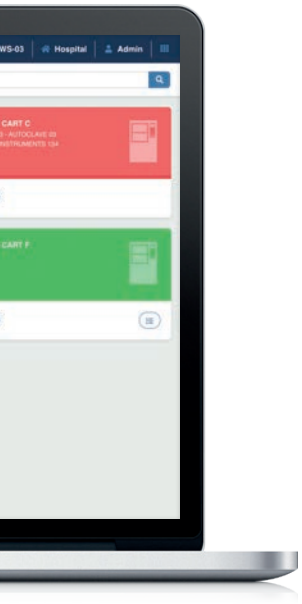
5

SHIPMENT

The system automatically prints delivery notes with indication of sterilization lots, suggesting the destination ward/customer for the trays.

HOSPITAL

In hospitals the system allows users to:



1

DELIVERY OF CLEAN INSTRUMENTS

Check deliveries and warehouse loads when sterilized instruments arrive.

2

CHECK IN

Check into the surgical block to use instruments in operating rooms. Instruments are matched to their cost centre and surgical operation; these information are saved by the system in order to trace all performed activities.

3

SHIPMENT OF DIRTY INSTRUMENTS

Pick-up of instruments to be sent to the CSSD. Instruments and trays are unloaded from the hospital warehouse and then loaded in the CSSD warehouse.

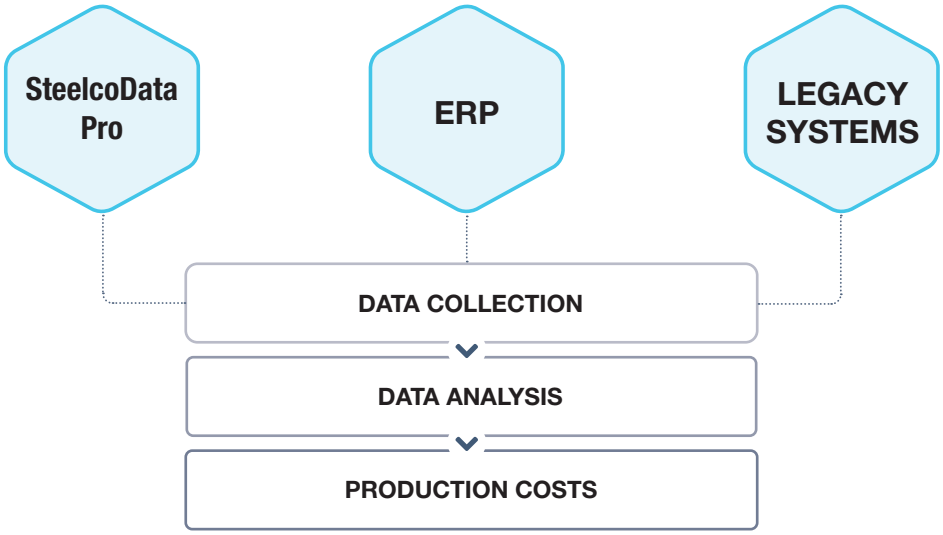
SteelcoData Pro can manage both hospitals' owned instruments than loans for use, with different invoicing rules.

Pro BENEFITS

TRACEABILITY	✔ full traceability in production departments
STARTUP	✔ Short startup times and implementation of new workstations
SECURITY & PRIVACY	✔ System administrators can grant deny and check authorizations to access the system and configure security policies ✔ Avoiding the access to unauthorized users
MONITORING ANALYSIS AND REPORTING SYSTEM	✔ Full and detailed reports to analyze key performance indicators and production costs ✔ Electronic record keeping and invoice automation
ENTERPRISE SYSTEM	✔ It can be used in small CSSDs or in bigger hospitals ✔ In case there are several CSSDs, the system can manage the process at multiple sites ✔ Sterilization can be carried out by an external company
PROCESS CONTROL	✔ Complete coverage of all areas/departments in the CSSD ✔ Support to all users in CSSDs using check-points, check-lists and help-on-line ✔ Visual and acoustic warnings in case of failed checks in every procedure ✔ Specific tools to support and speed up user effectiveness (for ex. optical and Datamatrix readers, RFID tags, wireless printers,…) ✔ Workflows can be completely customized
HELP DESK SUPPORT	✔ Available in English, German, Italian, French, Spanish, Russian and many other languages
MONITORING SERVICE	✔ The system and all devices can be remotely monitored by Helpdesk service

MANAGEMENT CONTROL AND COST ACCOUNTING

SteelcoData Pro records information about production, warehouse handlings, shipment, tracking times spent between the different departments/areas and procedures. For this reason it can easily analyze production costs for cost centre.



Management control functions allow the CSSD to reach fixed targets in operational scheduling, monitoring the gap between scheduled targets and results achieved using specific indicators.

Those information can be shared with the management in order to take proper actions.

The integration between SteelcoData Pro and any management software allows corporate management to get statistics and analyze production cost related to:

- user performances and costs
- working times and costs of equipments
- production times and costs
- time needed to dispatch orders and their delivery

HARDWARE DEVICES

All-in-one personal computers

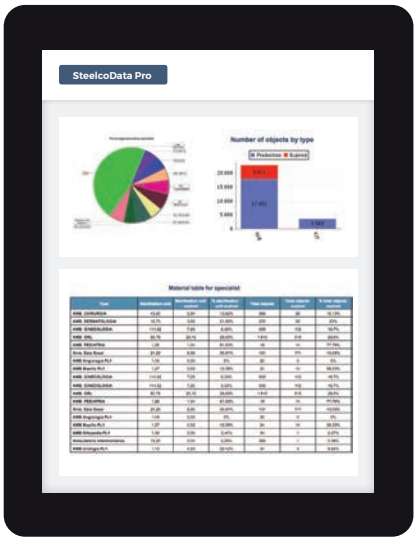
Barcode readers or RFID

Mobile devices

Datamatrix™ readers

Barcode printers

3D scanners



Pro

SURGICAL INSTRUMENT SCANNER

Surgical Instrument Scanner is a configurable smart traceability workstation that supports CSSD operators at packing stations by **quickly identifying groups of surgical instruments** thanks to **Artificial Intelligence technologies for recognition**.

The scanner works with or without DataMatrix or RFID and does not need any mark on the instruments.

The operator is then driven step by step in reassembling surgical instrument kits.

WORKSTATION COMPONENTS

CAMERA/S	PROJECTOR	TOUCH-SCREEN	VOICE RECOGNITION
Cameras to frame the instruments on the table and recognize them	Projector to guide the operator during the recomposition of the kit	Touch-screen to interact with traceability software	Microphone for voice instructions

KEY FEATURES

MODULAR

The workstation can be composed according to customer needs with single or double camera for a wider instrument identification surface.

See dedicated table.

POSITION INDEPENDENT

The system recognizes all the instruments on the workstation at once, independently of their positions on the table.

The recognition of the instruments is based only on physical parameters: shape, size, color, etc.

HANDLING BIG SETS

The system is suitable for big sets (100+ instruments) that can be recognized in few steps.

HANDS FREE CONTROL

The system can be integrated with a microphone for voice instructions (via a voice recognition system) instead of the usual touch screen to interact with the traceability software.

EASY PICK-UP

The workstation can also include a projector to guide the operator during the recomposition of the kit by highlighting the instruments to pick up in the proper order directly on the packing table.

INTEGRATION

The system is integrated with SteelcoData Pro hence it automatically communicates all kit information directly to the software.

MAIN BENEFITS

IMPROVED PATIENT SAFETY

- Recognition of the content of surgical kits
- Creation of detailed reports including check-list, number of instruments, comments and anomalies
- Tray accurately reassembled according to the CSSD requirements.
- Reduction of human error, increasing the quality of the whole process

TIME SAVING

- Recognition of the content of surgical kits
- Creation of detailed reports including check-list, number of instruments, comments and anomalies

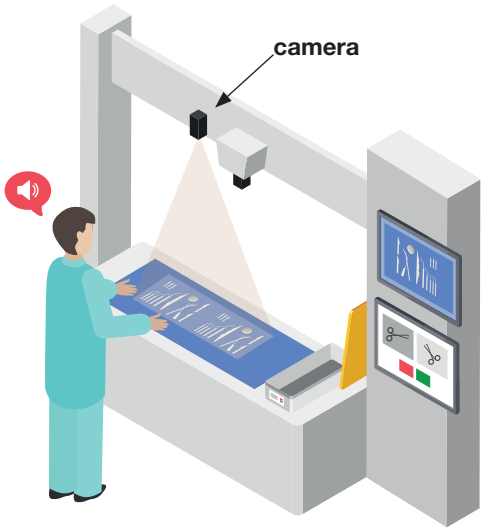
SIMPLIFIES COMPLEXITY

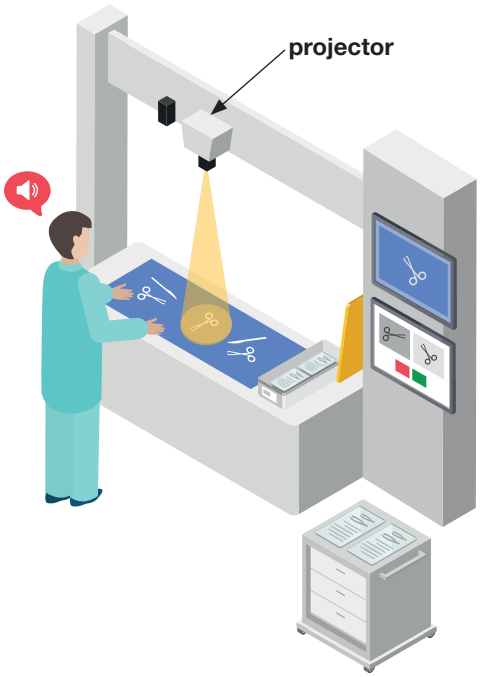
Suitable for complex and big surgical kits.

Manages the complete inventory of the CSSD instruments

Pro

SURGICAL INSTRUMENT SCANNER - WORKFLOW





RECOGNITION PHASE

The operator scans the barcode of the container. All the kit information is uploaded and key pieces of information are projected on the table. The instruments are placed on the table.

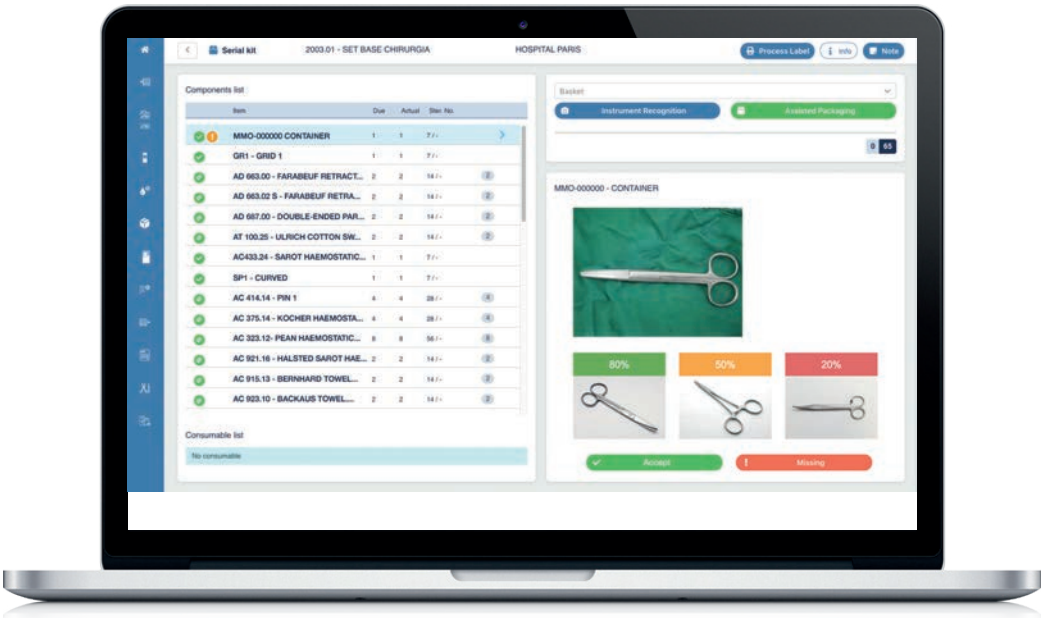
The combined work of the cameras with algorithms allows recognition of all the instruments at once.

Once the instruments are recognized, the traceability software is automatically updated and produces a report comprising a check-list and any possible irregularities (e.g., missing instruments, instruments not belonging to the current kit, etc).

KIT REASSEMBLING

A visual and/or acoustic signal guides the operator through kit's reassembly. Following a predefined order, the instruments are illuminated by the projector and ready to be placed in the container.

Once they are in the container, the system automatically lights up the next (group of) instrument(s), until all the tools are correctly positioned in the container, now ready for the sterilization.




SteelcoData Live
SteelcoData Pro
SteelcoData Ares

Miele Group Member

Headquarters

STEELCO S.p.A.
Via Balegante, 27 - 31039 Riese Pio X (TV) - ITALY
Ph. +39 0423 7561 - Fax +39 0423 755528
info@steelcogroup.com
www.steelcogroup.com

Branches

STEELCO ASIA
Puchong, Malaysia
info-asia@steelcogroup.com

STEELCO AUSTRIA
Wals-Siezenheim, Austria
info-at@steelcogroup.com

STEELCO BELGIUM
Mollem, Belgium
info-be@steelcogroup.com

STEELCO BENELUX
Vianen, Netherlands
info-benelux@steelcogroup.com

STEELCO CHINA
Shanghai, China
info-cn@steelcogroup.com

STEELCO FRANCE
Paris, France
info-fr@steelcogroup.com

STEELCO GERMANY (DACH Area)
Gütersloh, Germany
info-de@steelcogroup.com

STEELCO HUNGARY
Budapest, Hungary
info-hu@steelcogroup.com

STEELCO MEXICO
CDMX, Mexico
info-mx@steelcogroup.com

STEELCO NORDIC
Kgs. Lyngby, Denmark
info-nordic@steelcogroup.com

STEELCO NORGE
Nesbru, Norway
info-no@steelcogroup.com

STEELCO SPAIN
Madrid, Spain
info-es@steelcogroup.com

STEELCO SWITZERLAND
Spreitenbach, Switzerland
info-ch@steelcogroup.com

STEELCO USA
West Palm Beach, USA
info-usa@steelcogroup.com

DC-PD-02-SteelcoData Live & Pro EN Rev.03

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IQNET

The International Certification Network

www.iqnet-certification.com

www.imq.it

CERTIFICATO N.
CERTIFICATE N. **1050.2021**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA SALUTE E SICUREZZA SUL LAVORO
WE HEREBY CERTIFY THAT THE HEALTH AND SAFETY MANAGEMENT SYSTEM OPERATED BY

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 9/A - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 6-8 - 31039 RIESE PIO X (TV) Italy

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 45001:2018

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Vedere l'Allegato per l'attività (n°1 pagina)
View the Annex for the activity (n° 1 page)

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	23-08-2021	25-07-2023	22-08-2024

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19, 18, 29

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

CISQ

www.cisq.com

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www.imq.it

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IQNET
The International Certification Network
www.iqnet-certification.com

ALLEGATO CERTIFICATO N. **1050.2021**
ANNEX CERTIFICATE N.

Attività:
Activities:

Progettazione, produzione, installazione ed assistenza di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, sterilizzatori a vapore e/o a bassa temperatura, lavapadelle, lavastrumenti ad ultrasuoni ed apparecchi per il lavaggio, disinfezione e sterilizzazione chimica degli endoscopi termolabili. Progettazione, produzione, installazione ed assistenza di apparecchi per il lavaggio e disinfezione di vetreria, strumenti, carrelli, contenitori e parti di macchine speciali per il settore farmaceutico. Progettazione e commercializzazione di soluzioni disinfettanti per dispositivi medici invasivi e non invasivi. Commercializzazione di lavastrumenti per decontaminazione, sterilizzatori a vapore e relativi accessori. Commercializzazione di arredi e attrezzature/accessori a supporto dei processi di lavaggio, disinfezione, sterilizzazione e stoccaggio di attrezzature e strumenti. Processi: lavorazioni meccaniche, saldatura lamiere, assemblaggio, collaudo, imballaggio e spedizione di prodotti finiti.

Design, manufacturing, installation and service of washer disinfectors and trolley washers, washers for decontamination, steam and/or low temperature sterilizers, bedpan washers, ultrasonic washers and washers for the disinfection and the chemical sterilization of the thermolabile endoscopes. Design, manufacturing, installation and service of equipment for the washing and disinfection of glassware, instruments, trolleys, carboys and parts of special machines for the pharmaceutical industry. Commercialization of decontamination washers, steam sterilizers and their accessories. Commercialization of furniture/accessories to support washing, disinfection and sterilization processes as well as for the storage of instruments and tools. Processes: mechanical works, welding of metal sheets, assembly, testing, packaging and shipping of finished products.

Design, Produktion, Installation und Wartung von Reinigungsdesinfektionsautomaten und Wagenwaschanlagen zur Thermodesinfektion, Dekontaminationsgeraeten, Dampf- und / oder Niedertemperatur-Sterilisatoren, Steckbeckenspueler, Ultraschallreinigungsgeräten und Geräten zum Waschen, Desinfizieren und chemischen Sterilisieren von thermolabilen Endoskopen. Entwurf Herstellung Installation und Wartung von Anlagen zum Waschen und Desinfizieren von Glaswaren, Instrumenten, Wagen, Containern und Teilen von Spezialmaschinen für die pharmazeutische Industrie. Design und Marketing von Desinfektionslösungen für invasive und nicht-invasive Medizinprodukte. Vermarktung von Dekontaminationsgeräten, Dampfsterilisatoren und dazugehörigem Zubehör. Verkauf von Möbeln und Geräten / Zubehör zur Unterstützung der Reinigungsprozesse, Desinfektion, Sterilisation und Lagerung von Geräten und Werkzeugen.

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	23-08-2021	25-07-2023	22-08-2024

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
MS N° 0005MS
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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19, 18, 29

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IQNET

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Certificate

CISQ/IMQ has issued an IQNET recognized certificate that the organization:

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy

VIA DEL LAVORO 10/12/3/9A/6-8 - 31039 RIESE PIO X (TV) Italy

has implemented and maintains a

Occupational Health and Safety Management System

for the following scope: **Design, manufacturing, installation and service of washer disinfectors and trolley washers, washers for decontamination, steam and/or low temperature sterilizers, bedpan washers, ultrasonic washers and washers for the disinfection and the chemical sterilization of the thermolabile endoscopes. Design, manufacturing, installation and service of equipment for the washing and disinfection of glassware, instruments, trolleys, carboys and parts of special machines for the pharmaceutical industry. Commercialization of decontamination washers, steam sterilizers and their accessories. Commercialization of furniture/accessories to support washing, disinfection and sterilization processes as well as for the storage of instruments and tools. Processes: mechanical works, welding of metal sheets, assembly, testing, packaging and shipping of finished products.**

which fulfils the requirements of the following standard:

ISO 45001:2018

Issued on: **2023/07/25**
Expires on: **2024/08/22**

Registration Number: **IT – 134569-1050.2021**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

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The International Certification Network

www.iqnet-certification.com

CERTIFICATO N. **9191.SEE3**
CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE AMBIENTALE DI
WE HEREBY CERTIFY THAT THE ENVIRONMENTAL MANAGEMENT SYSTEM OPERATED BY

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy
SITI/SITES

Vedere gli Allegati per gli altri Siti (n° 3 allegati)
Vedere gli Allegati per gli altri Siti (n° 3 annexes)

E' CONFORME ALLA NORMA /*IS IN COMPLIANCE WITH THE STANDARD*

ISO 14001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, installazione e assistenza di sistemi di lavaggio, disinfezione e sterilizzazione in ambito medico sanitario, farmaceutico e per i laboratori di ricerca mediate i processi di lavorazioni meccaniche, saldatura lamiere, assemblaggio, collaudo, imballaggio e spedizione di prodotti finiti. Commercializzazione di apparecchiature, strumenti ed accessori per i processi di lavaggio, disinfezione e sterilizzazione

Design, production, installation and service of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories through the processes of machining, sheet metal welding, assembly, testing, packaging and shipping of the finished products.. Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes.

Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT-09

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	11/10/2017	21/07/2023	10/10/2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

IAF: 19,18,29

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

CISQ

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www.imq.it

ALLEGATO n. **9191.SEE3-1**
ANNEX No.

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy

Attività:
Activities:

Progettazione, produzione, installazione e assistenza di sistemi di lavaggio, disinfezione e sterilizzazione in ambito medico sanitario, farmaceutico e per i laboratori di ricerca mediate i processi di lavorazioni meccaniche, saldatura lamiere, assemblaggio, collaudo, imballaggio e spedizione di prodotti finiti. Commercializzazione di apparecchiature, strumenti ed accessori per i processi di lavaggio, disinfezione e sterilizzazione Commercializzazione di apparecchiature, strumenti ed accessori per i processi di lavaggio, disinfezione e sterilizzazione. Commercializzazione di apparecchiature, strumenti ed accessori per i processi di lavaggio, disinfezione e sterilizzazione.

Design, production, installation and service of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories through the processes of machining, sheet metal welding, assembly, testing, packaging and shipping of the finished products. Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A: STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO: STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9191.SEE3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9191.SEE3

DATE	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	11/10/2017	21/07/2023	10/10/2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9191.SEE3
This document is part of certificate n. 9191.SEE3

IAF: 18,19,29

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
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ALLEGATO n. **9191.SEE3-2**
ANNEX No.

STEELCO SPA

VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 9A - 31039 RIESE PIO X (TV) Italy

Attività:
Activities:

Produzione di sistemi di lavaggio, disinfezione e sterilizzazione in ambito medico sanitario, farmaceutico e per i laboratori di ricerca

Production of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A: STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO: STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9191.SEE3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9191.SEE3

DATE	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	11/10/2017	21/07/2023	10/10/2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9191.SEE3
This document is part of certificate n. 9191.SEE3

IAF: 18,19

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
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ALLEGATO n. **9191.SEE3-3**
ANNEX No.

STEELCO SPA

VIA DEL LAVORO 6-8 - 31039 RIESE PIO X (TV) Italy

Attività:
Activities:

Produzione di sistemi di lavaggio, disinfezione e sterilizzazione in ambito medico sanitario, farmaceutico e per i laboratori di ricerca. Magazzino prodotto finito

Production of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories. Warehouse for finished products

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A: STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO: STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9191.SEE3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9191.SEE3

DATE	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	11/10/2017	21/07/2023	10/10/2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9191.SEE3
This document is part of certificate n. 9191.SEE3

IAF: 19

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STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 9A - 31039 RIESE PIO X (TV) Italy
VIA DEL LAVORO 6-8 - 31039 RIESE PIO X (TV) Italy

has implemented and maintains a
Environmental Management System

for the following scope:
Design, production, installation and service of cleaning, disinfection and sterilisation systems for healthcare, pharmaceutical and research laboratories through the processes of machining, sheet metal welding, assembly, testing, packaging and shipping of the finished products.. Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes Marketing of equipment, instruments and accessories for washing, disinfection and sterilisation processes.

which fulfils the requirements of the following standard:

ISO 14001:2015

Issued on: **2023/07/21**
Expires on: **2026/10/10**

Registration Number: **IT – 112291-9191.SEE3**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

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Steelco

Miele Group Member

Declaration of Conformity UE

VS 4 G2 E - EI - EV - I - V

Type of steam supply:
E = internal generator with **E**lectric heating
EI = internal generator with **E**lectric heating + **I**ndirect steam
EV = Internal generator with **E**lectric heating + direct steam (**V**apour)
I = internal generator with **I**ndirect steam heating
V = Direct centralized steam (**V**apour) without internal generator

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/1 E G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/1 EI G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente

Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/1 EV G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/1 I G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/1 V G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/2 E G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/2 EI G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/2 EV G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/2 I G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION UE DE CONFORMITÉ
EU KONFORMITÄTS-ERKLÄRUNG
DECLARACIÓN UE DE CONFORMIDAD

CE 0051

The undersigned, officer of the under-written company, hereby declares that the product:
Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:
El firmante, como representante legal de la empresa indicada, declara que el producto:

Name/Type:
Nome/Modello:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
VS 4/2 V G2

Serial/Lot N.:
N° di Serie/Lotto:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
XXXXX

[EN] Referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules.
This declaration is of conformity is issued under the sole responsibility of the manufacturer and written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..
The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.
Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1652/MDD valid till **2024/05/26**.
The device has built-in a pressure vessel assembly type xx xxx xx xx and all its declarations of conformity are attached to this document.

[IT] In riferimento alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante ed è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1652/MDD con validità fino al **26/05/2024**.
Il dispositivo incorpora un assieme in pressione modello xx xxx xx xx e le relative dichiarazioni di conformità sono allegate alla presente documentazione.

[FR] En référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant et est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1652/MDD avec validité jusqu'à **26/05/2024**.
Le dispositif incorpore un ensemble en pression modèle xx xxx xx xx et les déclarations de conformité sont jointes à ce document.

[DE] Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller und in Übereinstimmung mit Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.
Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.
Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1652/MDD, gültig bis zum **26/05/2024**, bestätigt wird.
Das Gerät verfügt über einen Druckbehälter Typ xx xxx xx xx und alle Konformitätserklärungen sind diesem Dokument beigefügt.

[ES] En referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante y es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1652/MDD con validez hasta a **26/05/2024**.
El aparato incorpora junto un recipientes en presión modelo xx xxx xx xx y las relativas declaraciones de conformidad resultan anexas a la presente documentación.

Applied directives:
Direttive applicate:
Directives appliquées:
Angewandte Richtlinien:
Directivas aplicadas:
93/42/EEC (Medical Devices Directive and s.m.i. - 2007/47/EC**)**
2011/65/EU (RoHS 2 Directive)

[GMDN: 38671]

RIESE PIO X, dd/mm/yyyy

Managing Director
Direttore Generale
Director Général
Geschäftsführer
Gerente
Fabio Zardini
Steelco S.p.A.

www.imq.it

CISQ is a member of

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CERTIFICATO N.
CERTIFICATE N. 9124.IST2

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n° 5 pagine)
View the Annexes for the Operative Units (n° 5 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, immissione in commercio, installazione, assistenza e commercializzazione di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, sterilizzatori a bassa temperatura, lavapadelle, lavastrumenti ad ultrasuoni per dispositivi medici ed apparecchi per il lavaggio, disinfezione e sterilizzazione chimica degli endoscopi termolabili e relativi accessori. Gestione della progettazione e della produzione, immissione in commercio di sterilizzatrici a vapore, autoclavi a vapore per disinfezione di dispositivi medici quali materassi e cuscini ospedalieri e relativi accessori. Gestione della progettazione e della produzione, immissione in commercio e commercializzazione di soluzioni disinfettanti per dispositivi medici invasivi e non invasivi

Design, manufacture, installation, placing on the market, service and trading of washer disinfectors for instruments and trolleys, instruments decontamination units, low temperature sterilizers, bedpan washers, instruments washers by ultrasounds for medical devices and equipment for the chemical washing, disinfection and sterilization of thermolable endoscopes and related accessories. Design and manufacture management, placing on the market of steam sterilizers units, steam disinfectors of medical devices, such as hospital mattresses and pillows and related accessories. Design and manufacture management, placing on the market and trading of disinfectant solutions for invasive and noninvasive medical devices

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-08-30	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

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ERTIFICATO N.
CERTIFICATE N. 9120.IST1

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n° 5 pagine)
View the Annexes for the Operative Units (n° 5 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, installazione e assistenza di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, sterilizzatori a vapore e/o a bassa temperatura, lavastrumenti ad ultrasuoni, passacarrelli e relativi accessori per i settori laboratorio e stabulario. Progettazione, produzione, installazione ed assistenza di apparecchi e relativi accessori di apparecchi per il lavaggio e disinfezione di vetreria, strumenti, carrelli, contenitori e parti di macchine speciali per il settore farmaceutico. Commercializzazione di lavastrumenti per decontaminazione, sterilizzatori a vapore e relativi accessori. Commercializzazione di arredi ed attrezzature/accessori a supporto dei processi di lavaggio, disinfezione, sterilizzazione e stoccaggio di attrezzature e strumenti

Design, manufacture, installation and service of washer disinfectors for instruments and trolleys, instruments decontamination units, steam sterilizers units and/or low temperature sterilizers, instruments washers by ultrasounds, passthrough cabinets and related accessories for laboratory and life science industries. Design, manufacture, installation and service of washing and disinfecting equipment as washer disinfectors for instruments and trolleys, containers and special machine parts for pharmaceutical industry. Sale of instruments decontamination units, steam sterilizers units and related accessories. Sale of furniture and equipment/accessories for washing, disinfection, sterilization and storage processes for tools and instruments

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19, 18, 29

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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www.imq.it

FEDERAZIONE CISQ

www.cisq.com

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ALLEGATO N. **9120.IST1-1**
ANNEX N.

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV)

Attività:
Activities:

Progettazione, produzione, installazione, assistenza e commercializzazione di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, sterilizzatori a bassa temperatura, lavastrumenti ad ultrasuoni e relativi accessori per i settori laboratorio e stabulario. Progettazione, produzione di sterilizzatrici a vapore (secondo procedura di OBL con fornitore esterno)
Design, manufacture, installation, service and trading of washer disinfectors for instruments and trolleys, instruments decontamination units, low temperature sterilizers, instruments washers by ultrasounds and related accessories for laboratory and life science industries. Design, manufacture of steam sterilizers units (according to procedure of OBL with external supplier)

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9120.IST1
This document is a part of certificate n. 9120.IST1

IAF: 19, 18, 29

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ
Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com
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CSQ
www.imq.it

ALLEGATO N. **9120.IST1-2**
ANNEX N.

STEELCO SPA

VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV)

Attività:
Activities:

Produzione (lavorazioni meccaniche e conservazione materie prime)
Manufacture (mechanical processing and storing raw materials)

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9120.IST1
This document is a part of certificate n. 9120.IST1

IAF: 18

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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ALLEGATO N. **9120.IST1-3**
ANNEX N.

STEELCO SPA

VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV)

Attività:
Activities:

Progettazione, produzione, installazione ed assistenza di apparecchi e relativi accessori per il lavaggio e disinfezione di vetreria, strumenti, carrelli, contenitori e parti di macchine speciali per il settore farmaceutico
Design, manufacture, installation and service of equipment and related accessories for washing and disinfecting instruments and trolleys, containers and special machine parts for pharmaceutical industry

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9120.IST1
This document is a part of certificate n. 9120.IST1

IAF: 19, 18

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com
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ALLEGATO N. **9120.IST1-4**
ANNEX N.

STEELCO SPA

VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV)

Attività:
Activities:

Progettazione, produzione, installazione ed assistenza di lavastrumenti e lavacarrelli a termodisinfezione, lavastrumenti per decontaminazione, apparecchi per il lavaggio/disinfezione e relativi accessori
Design, manufacture, installation and service of washer disinfectors for instruments and trolleys, instruments decontamination units, washing/disinfection devices and related accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION* 2006-05-05	EMISSIONE CORRENTE *CURRENT ISSUE* 2021-03-25	SCADENZA *EXPIRY* 2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
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This document is a part of certificate n. 9120.IST1

IAF: 19

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ALLEGATO N. **9120.IST1-5**
ANNEX N.

STEELCO SPA

VIA DEL LAVORO 9/A - 31039 RIESE PIO X (TV)

Attività:
Activities:

Progettazione e produzione di passacarrelli, accessori e componenti delle lavastrumenti o sterilizzatrici quali i sistemi di trasporto automatici
Design and manufacture of passthrough cabinets, accessories and components of instrument washers or sterilizers as the automatic transport systems

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A STEELCO SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO STEELCO SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9120.IST1
FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9120.IST1

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2006-05-05	2021-03-25	2024-04-22

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
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Il presente documento integra il certificato n. 9120.IST1
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IAF: 19, 18

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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

STEELCO SPA

VIA BALEGANTE 27 - 31039 RIESE PIO X (TV)
VIA DEL LAVORO 12 - 31039 RIESE PIO X (TV)
VIA DEL LAVORO 10 - 31039 RIESE PIO X (TV)
VIA DEL LAVORO 3 - 31039 RIESE PIO X (TV)
VIA DEL LAVORO 9/A - 31039 RIESE PIO X (TV)

has implemented and maintains a
Quality Management System
for the following scope:

Design, manufacture, installation and service of washer disinfectors for instruments and trolleys, instruments decontamination units, steam sterilizers units and/or low temperature sterilizers, instruments washers by ultrasounds, passthrough cabinets and related accessories for laboratory and life science industries. Design, manufacture, installation and service of washing and disinfecting equipment as washer disinfectors for instruments and trolleys, containers and special machine parts for pharmaceutical industry. Sale of instruments decontamination units, steam sterilizers units and related accessories. Sale of furniture and equipment/accessories for washing, disinfection, sterilization and storage processes for tools and instruments

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: **2021 - 03 - 25**
Expires on: ***2024 - 04 - 22***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 52077

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

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CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com