CERTIFICATO CE

Certificato n. 909/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

STEELCO SPA

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

mantiene nello stabilimento di:

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

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

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

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

un sistema qualità che assicura la conformità dei seguenti prodotti:

Lavapadelle a termodisinfezione per uso medicale

Termodisinfettori per uso medicale

Lavaendoscopi per uso medicale

Lavastrumenti per decontaminazione ad uso medicale

Lava disinfettatrice-sterilizzatrice chimica per endoscopi

Sterilizzatore al perossido di idrogeno

Soluzione sterilizzante al perossido di idrogeno

Disinfettori termici e/o chimici per uso medicale

Soluzione sterilizzante alla formaldeide

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Digitally signed by Ceaicovschi Tudor
Date: 2023.05.12 11:39:49 EEST
Reason: MoldSign Signature
Location: Moldova

Emesso il:	2006-03-10
Data aggiornamento:	2020-09-11
Sostituisce:	2020-07-03
Data scadenza:	2024-05-26

Giorgi Fulvio
IMQ DocuSign

CERTIFICATO CE

Certificato n. 909/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Riferimento pratiche IMQ:

DM17-0017730-01; DM17-0016713-01; DM17-0020271-01; DM18-0027447-01; DM18-0030229-01; DM18-0032276-01; DM19-0034875-01; DM18-0033656-01; DM19-0040534-01; DM19-0044781-01; DM20-0048677-01; DM20-0048683-01; DM20-0052515-01; DM20-0052521-01; DM20-0048679-01; DM20-0055248-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2006-03-10
Data aggiornamento:	2020-09-11
Sostituisce:	2020-07-03
Data scadenza:	2024-05-26

Giorgi Fulvio
IMQ

DocuSign

CERTIFICATO CE

Certificato n. 909/MDD

Allegato

Lavapadelle a termodisinfezione per uso medicale

Termodisinfettori per uso medicale

Lavaendoscopi per uso medicale

Lavastrumenti per decontaminazione ad uso medicale

Lava disinfettatrice-sterilizzatrice chimica per endoscopi

Sterilizzatore al perossido di idrogeno

Soluzione sterilizzante al perossido di idrogeno

Disinfettori termici e/o chimici per uso medicale

Soluzione sterilizzante alla formaldeide

Modd. come da documento allegato "ELENCO PRODOTTI" rev. 02 del 02/09/2020, valido solo se provvisto del timbro IMQ; tale allegato costituisce parte integrante e sostanziale del presente certificato.

Emesso il:	2006-03-10
Data aggiornamento:	2020-09-11
Sostituisce:	2020-07-03
Data scadenza:	2024-05-26

Giorgi Fulvio
IMQ

DocuSign

EC CERTIFICATE

Certificate No 909/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

STEELCO SPA

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

manages in the factory of:

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

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

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

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

a quality assurance system ensuring the conformity of the following products:

Flusher disinfectors / Bedpan washers

Washer disinfectors

Endoscope washers

Decontamination clenears

Chemical washer disinfector and sterilizer for endoscopes

Hydrogen peroxide sterilizer

Hydrogen peroxide sterilizing agent

Thermal and/or chemical washer disinfectors for medical purpose

Formaldehyde sterilizing solution

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Date:	2006-03-10
Updated:	2020-09-11
Substitution Date:	2020-07-03
Expiry Date:	2024-05-26

Giorgi Fulvio
IMQ DocuSign

EC CERTIFICATE

Certificate No 909/MDD

Full Quality Assurance System Approval Certificate

Reference to IMQ files Nos:

DM17-0017730-01; DM17-0016713-01; DM17-0020271-01; DM18-0027447-01; DM18-0030229-01; DM18-0032276-01; DM19-0034875-01; DM18-0033656-01; DM19-0040534-01; DM19-0044781-01; DM20-0048677-01; DM20-0048683-01; DM20-0052515-01; DM20-0052521-01; DM20-0048679-01; DM20-0055248-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2006-03-10
Updated:	2020-09-11
Substitution Date:	2020-07-03
Expiry Date:	2024-05-26

Giorgi Fulvio
IMQ DocuSign

EC CERTIFICATE

Certificate No 909/MDD

Annex

Flusher disinfectors / Bedpan washers

Washer disinfectors

Endoscope washers

Decontamination clenears

Chemical washer disinfector and sterilizer for endoscopes

Hydrogen peroxide sterilizer

Hydrogen peroxide sterilizing agent

Thermal and/or chemical washer disinfectors for medical purpose

Formaldehyde sterilizing solution

Type ref. as to attached document "LIST OF PRODUCTS" rev. 02 dated 2020/09/02, valid only if provided with IMQ stamp; this annex is integral and substantial part of this certificate.

Date:	2006-03-10
Updated:	2020-09-11
Substitution Date:	2020-07-03
Expiry Date:	2024-05-26

Giorgi Fulvio
IMQ

DocuSign

Lavapadelle a termodisinfezione per uso medicale della serie **BP** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE		CARROZZERIA		ALLESTIMENTO
			NUMERO	MOVIMENTO	LARGHEZZA	ALTEZZA	
Serie: **BP** Marca: Steelco	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 750W a 9900 W	1 o 2	MANUALE / SEMI-AUTOMATICA / AUTOMATICA	STANDARD / RIDOTTA / MAGGIORATA	STANDARD / ALTA	STANDARD / E

Nomi commerciali modelli:	Fascicolo tecnico:
BP 100 M, BP 100 M9, BP 100 A, BP 100 A9, BP 100 H, BP 100 H5, BP 100 HS, BP 100 HA, BP 100 HA5, BP 100 HE, BP 100 HSE, BP 100 HAE, BP 100 HSER, BP 100 HL, BP 100 HLS, BP 100 HLA, BP 100 HL2MM, BP 100 HL2AM, BP 100 HXL	**DT-FT-01_M**

Termodisinfettori per uso medicale della serie **DS** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE		CARROZZERIA	OPTIONAL
			NUMERO	MOVIMENTO		
Serie: **DS** Marca: Steelco	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 2200W a 37000W	1 o 2	MANUALE / AUTOMATICA	STANDARD / ALTA	ASCIUGATURA / 3 o 4 DOSATORI / DEPURATA

Nomi commerciali modelli:	Fascicolo tecnico:
DS 50, DS 50 D, DS 50 DRS, DS 50 DRSD, DS 50 HDRS, DS 50 HDRSD, DS 50/2, DS 50/2 D, DS 50/2 DRS, DS 50/2 DRSD	**DT-FT-04_M**
DS 500, DS 500 D, DS 500 DRS, DS 500 DRSD, DS 500 DRS4, DS 500 LED, DS 500 LEDD, DS 500 SC, DS 500 SCD, DS 500 SCL, DS 500 SCDL, DS 500 CL, DS 500 CDL, DS 600/1, DS 600/1 D, DS 600/2, DS 600/2 D, DS 600 C, DS 600 CD, DS 600/1 1S, DS 600/2 1S, DS 610/1, DS 610/1 D, DS 610/2, DS 610/2 D, DS 610/1 1S, DS 610/1 2S, DS 610/2 1S, DS 610/2 2S, DS 610/1 SL, DS 610/1 SLD, DS 610/2 SL, DS 610/2 SLD, DS 610/1 SL1S, DS 610/1 SL2S, DS 610/2 SL1S, DS 610/2 SL2S	**DT-FT-03_M**
DS 650, DS 700, DS 750, DS 750 1S, DS 750 2S, DS 750 3S, DS 800, DS 800 1S, DS 800 2S, DS 800 3S,	**DT-FT-06_M**
DS 900, DS 900 1S, DS 900 2S, DS 900 3S, DS 1000, DS 1000 1S, DS 1000 2S, DS 1000 3S, DS 900 N, DS 900 N1S, DS 900 N2S, DS 900 N3S, DS 1000 N, DS 1000 N1S, DS 1000 N2S, DS 1000 N3S	**DT-FT-05_M**

Termodisinfettori per uso medicale della serie **WD** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA
Serie: **WD** Marca: Steelco	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 13500 W a 25000W

Nomi commerciali modelli:	Fascicolo tecnico:
WD 1110	**DT-FT-06_M**
WD 1115	**DT-FT-05_M**

2020-09-11

Termodisinfettori per uso medicale della serie **TW** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	STAZIONI NUMERO
Serie: **TW** Marca: Steelco	*Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 3000W a 140000W	Da 2 a 5

Nomi commerciali modelli: **TW 3000/2, TW 3000/3, TW 3000/4, TW 3000/5**
Fascicolo tecnico: **DT-FT-09_M**

Termodisinfettori per uso medicale della serie **LC** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE		DIMENSIONI LONGITUDINALI
			NUMERO	MOVIMENTO	
Serie: **LC** Marca: Steelco	*Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 1200W a 201000W	1 o 2	MANUALE / AUTOMATICA	/2 = Da 1500 mm a 2999 mm /3 = Da 3000 mm a 3999 mm /4 = Da 4000 mm a 4999 mm

Nomi commerciali modelli: **LC 20/1, LC 20/2**
Fascicolo tecnico: **DT-FT-12_M**

Disinfettori termici e/o chimici per uso medicale* della serie **LC** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE MOVIMENTO	DIMENSIONI LONGITUDINALI
Serie: **LC** Marca: Steelco	*Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 1200W a 201000W	MANUALE / AUTOMATICA	/2 = Da 1500 mm a 2999 mm /3 = Da 3000 mm a 3999 mm /4 = Da 4000 mm a 4999 mm

Nomi commerciali modelli: **LC 70/2, LC 70/3, LC 80/2, LC 80/3, LC 80/4, LC 80/2 BOT, LC 80/3 BOT, LC 80/4 BOT**
Fascicolo tecnico: **DT-FT-08_M**

***Nota:** Per la Serie LC 80 e LC 70 esistono due tipologie di disinfezione: termica o ibrida (termica o chimica). Tale distinzione è garantita e riconoscibile dal codice prodotto finito riportato in etichetta matricola.

Lavastrumenti per decontaminazione ad uso medicale con ausilio di ultrasuoni della serie **US** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE NUMERO
Serie: **US** Marca: Steelco	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Fino a 14000W	1 o 2

Nomi commerciali modelli:
US 80 — Fascicolo tecnico: **DT-FT-20_M**
US 100, US 200/1, US 200/2, US 200/3, US 200/4, US 100 XL — **DT-FT-13_M**
US 300 — **DT-FT-21_M**
US 900, US 1000 — **DT-FT-07_M**

2020-09-11

Lavastrumenti per decontaminazione ad uso medicale della serie **DC** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE NUMERO
Serie: **DC** Marca: Steelco	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Fino a 10000W	1 o 2

Nomi commerciali modelli:
DC 100, DC 200/1, DC 200/2
DC 1000/1, DC 1000/2

Fascicolo tecnico:
DT-FT-17_M
DT-FT-19_M

Lavaendoscopi per uso medicale della serie **EW 2** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE NUMERO
Serie: **EW 2** Marca: Steelco	*Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Fino a 9100W	1 o 2

Nomi commerciali modelli:
EW 2/1, EW 2/2, EW 2/1 2S, EW 2/2 2S, EW 2/1 3S, EW 2/2 3S

Fascicolo tecnico:
DT-FT-10_M

Lava disinfettatrice-sterilizzatrice chimica per endoscopi della serie EW 1 comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE NUMERO
Serie: **EW 1** Marca: Steelco	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Fino a 6100 W	Da 1 a 4

Nomi commerciali modelli:
EW 1, EW 1 S, EW 1 DUAL H

Fascicolo tecnico:
DT-FT-18_M

Sterilizzatore al perossido di idrogeno della serie **PL** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE NUMERO
Serie: **PL** Marca: Steelco	*Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Fino a 5000 W	1 o 2

Nomi commerciali modelli:
PL 70/1, PL 70/2, PL 130/1, PL 130/2, PL 40/1

Fascicolo tecnico:
DT-FT-27_M

2020-09-11

Soluzione sterilizzante al perossido di idrogeno della serie **SteelcoPro PL** comprende le seguenti varianti e denominazioni:

	CONCENTRAZIONE
Serie: **SteelcoPro PL** Marca:	**58% di H_2O_2**

Nomi commerciali modelli:	Fascicolo tecnico:
SteelcoPro PL	**DT-FT-17_C**

Soluzione sterilizzante alla formaldeide della serie **SteelcoPro LTSF** comprende le seguenti varianti e denominazioni:

	CONCENTRAZIONE
Serie: **SteelcoPro LTSF** Marca:	**Dal 10% al 20%**

Nomi commerciali modelli:	Fascicolo tecnico:
SteelcoPro LTSF 4; SteelcoPro LTSF 6; SteelcoPro LTSF 8	**DT-FT-13_C**

2020-09-11

Lavapadelle a termodisinfezione per uso medicale della serie **BP** comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE		CARROZZERIA		ALLESTIMENTO
			NUMERO	MOVIMENTO	LARGHEZZA	ALTEZZA	
Serie: **PWD** Marca: Miele	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 750W a 6900 W	1 o 2	MANUALE / SEMI-AUTOMATICA / AUTOMATICA	STANDARD / RIDOTTA / MAGGIORATA	STANDARD / ALTA	STANDARD / E

Nomi commerciali modelli:	Fascicolo tecnico:
PWD 8541 MD, PWD 8541 AD, PWD 8545 MD, PWD 8545 SAD, PWD 8545 AD, PWD 8546, PWD 8546 AD, PWD 8549, PWD 8543	**DT-FT-01_M**

Termodisinfettori per uso medicale della serie comprende le seguenti varianti e denominazioni:

	ALIMENTAZIONE	POTENZA	PORTE		CARROZZERIA	ALLESTIMENTO
Serie: **PWD** Marca: Miele	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 2220W a 37000W	1 o 2	MANUALE / AUTOMATICA	STANDARD / ALTA	ASCIUGATUIRA / 3 O 4 DOSATORI / DEPURATA

Nomi commerciali modelli:	Fascicolo tecnico:
PWD 8531, PWD 8531 WS, PWD 8532, PWD 8532 WS, PWD 8534, PWD 8534 WS	**DT-FT-04_M**
PWD 6121, PWD 6122, PWD 6121 TH1, PWD 6122 TH1, PWD 6121 TH2, PWD 6122 TH2	**DT-FT-03_M**

2020-09-11

Flusher Disinfectors / Bedpan washers for medical purpose BP line includes the following variants and names:

	FEEDING	POWER	DOORS		BODY		SET UP
			NUMBER	MOVEMENT	WIDTH	HEIGHT	
Line: **BP** Trade Mark: Steelco	*Single-phase* 110V / 60Hz 220-240V / 50-60Hz *Three-phase* 200-230V / 50-60Hz 380-480V / 50-60Hz	From 750W to 9900W	1 or 2	MANUAL / SEMI-AUTOMATIC / AUTOMATIC	STANDARD / REDUCED / INCREASED	STANDARD / HIGH	STANDARD / E

Trade names: Technical file:

BP 100 M, BP 100 M9, BP 100 A, BP 100 A9, BP 100 H, BP 100 H5, BP 100 HS, BP 100 HA, BP 100 HA5, BP 100 HE, BP 100 HSE, BP 100 HAE, BP 100 HSER, BP 100 HL, BP 100 HLS, BP 100 HLA, BP 100 HL2MM, BP 100 HL2AM, BP 100 HXL — **DT-FT-01_M**

Washer Disinfectors for medical purpose DS line include the following variants and names:

	FEEDING	POWER	DOORS		BODY	OPTIONALS
			NUMBER	MOVEMENT		
Line: **DS** Trade Mark: Steelco	*Single-phase* 110V / 60Hz 220-240V / 50-60Hz *Three-phase* 200-230V / 50-60Hz 380-480V / 50-60Hz	From 2220W to 37000W	1 or 2	MANUAL / AUTOMATIC	STANDARD / HIGH	WITH DRYING / 3 or 4 DOSING PUMPS / WITH WATER SOFTNER

Trade names: Technical file:

DS 50, DS 50 D, DS 50 DRS, DS 50 DRSD, DS 50 HDRS; DS 50 HDRSD; DS 50/2, DS 50/2 D, DS 50/2 DRS, DS 50/2 DRSD — **DT-FT-04_M**

DS 500, DS 500 D, DS 500 DRS, DS 500 DRSD, DS 500 DRS4, DS 500 LED, DS 500 LEDD, DS 500 SC, DS 500 SCD, DS 500 SCL, DS 500 SCDL, DS 500 CL, DS 500 CDL, DS 600/1, DS 600/1 D, DS 600/2, DS 600/2 D, DS 600 C, DS 600 CD, DS 600/1 1S, DS 600/2 1S, DS 610/1, DS 610/1 D, DS 610/2, DS 610/2 D, DS 610/1 1S, DS 610/1 2S, DS 610/2 1S, DS 610/2 2S, DS 610/1 SL, DS 610/1 SLD, DS 610/2 SL, DS 610/2 SLD, DS 610/1 SL1S, DS 610/1 SL2S, DS 610/2 SL1S, DS 610/2 SL2S — **DT-FT-03_M**

DS 650, DS 700, DS 750, DS 750 1S, DS 750 2S, DS 750 3S, DS 800, DS 800 1S, DS 800 2S, DS 800 3S — **DT-FT-06_M**

DS 900, DS 900 1S, DS 900 2S, DS 900 3S, DS 1000, DS 1000 1S, DS 1000 2S, DS 1000 3S DS 900 N, DS 900 N1S, DS 900 N2S, DS 900 N3S, DS 1000 N, DS 1000 N1S, DS 1000 N2S, DS 1000 N3S. — **DT-FT-05_M**

Washers Disinfectors for medical purpose WD line include the following variants and names:

	FEEDING	POWER
Line: **WD** Trade Mark: Steelco	*Single-phase* 110V / 60Hz 220-240V / 50-60Hz *Three-phase* 200-230V / 50-60Hz 380-480V / 50-60Hz	From 13500W to 25000W

Trade names: Technical file:

WD 1110 — **DT-FT-06_M**

WD 1115 — **DT-FT-05_M**

2020-09-11

Washer Disinfectors for medical purpose TW line includes the following variants and names:

	FEEDING	POWER	STATIONS NUMBER
Line: **TW** Trade Mark: Steelco	*Three-phase* 200-230V / 50-60Hz 380-480V / 50-60Hz	From 3000W to 140000W	From 2 to 5

Trade names: **TW 3000/2, TW 3000/3, TW 3000/4, TW 3000/5**

Technical file: **DT-FT-09_M**

Thermal Washer Disinfectors for medical purpose LC line includes the following variants and names:

	FEEDING	POWER	DOORS NUMBER	DOORS MOVEMENT	LONGITUDINAL DIMENSIONS
Line: **LC** Trade Mark: Steelco	*Three-phase* 200-230V /50-60Hz 380-480V / 50-60Hz	From 1200W to 201000W	1 or 2	MANUAL / AUTOMATIC	/2 = From 1500 mm to 2999 mm /3 = From 3000 mm to 3999 mm /4 = From 4000 mm to 4999 mm

Trade names: **LC 20/1, LC 20/2.**

Technical file: **DT-FT-12_M**

Thermal and/or Chemical Washer Disinfectors for medical purpose* LC line includes the following variants and names:

	FEEDING	POWER	DOORS MOVEMENT	LONGITUDINAL DIMENSIONS
Line: **LC** Trade Mark: Steelco	*Three-phase* 200-230V /50-60Hz 380-480V / 50-60Hz	From 1200W to 201000W	MANUAL / AUTOMATIC	/2 = From 1500 mm to 2999 mm /3 = From 3000 mm to 3999 mm /4 = From 4000 mm to 4999 mm

Trade names: **LC 70/2, LC 70/3, LC 80/2, LC 80/3, LC 80/4, LC 80/2 BOT, LC 80/3 BOT, LC 80/4 BOT**

Technical file: **DT-FT-08_M**

***Note:** For the LC 80 and LC 70 Series there are two types of disinfection: thermal or hybrid (thermal or chemical). This distinction is guaranteed and recognizable by the finished product code shown on the label.

Decontamination cleaners for medical purpose with ultrasonic function US line includes the following variants and names:

	FEEDING	POWER	DOORS NUMBER
Line: **US** Trade Mark: Steelco	*Single-phase* 110V / 60Hz 220-240V / 50-60Hz *Three-phase* 200-230V /50-60Hz 380-480V / 50-60Hz	Up to 14000W	1 or 2

Trade names:

Technical file:

US 80 — **DT-FT-20_M**

US 100, US 200/1, US 200/2, US 200/3, US 200/4, US 100 XL — **DT-FT-13_M**

US 300 — **DT-FT-21_M**

US 900, US 1000 — **DT-FT-07_M**

2020-09-11

Decontamination cleaners for medical purpose DC line includes the following variants and names:

	FEEDING	POWER	DOORS NUMBER
Line: **DC** Trade Mark: Steelco	*Single-phase* 110V / 60Hz 220-240V / 50-60Hz *Three-phase* 200-230V /50-60Hz 380-480V / 50-60Hz	Up to 10000W	1 or 2

Trade names:	Technical file:
DC 100, DC 200/1, DC 200/2	**DT-FT-17_M**
DC 1000/1, DC 1000/2	**DT-FT-19_M**

Endoscope washers for medical purpose EW 2 line includes the following variants and names:

	FEEDING	POWER	DOORS NUMBER
Line: **EW 2** Trade Mark: Steelco	*Three-phase* 200-230V /50-60Hz 380-480V / 50-60Hz	Up to 9100W	1 or 2

Trade names:	Technical file:
EW 2/1, EW 2/2, EW 2/1 2S, EW 2/2 2S, EW 2/1 3S, EW 2/2 3S	**DT-FT-10_M**

Chemical washer disinfector and sterilizer for endoscopes EW 1 line includes the following variants and names:

	FEEDING	POWER	DOORS NUMBER
Line: **EW 1** Trade Mark: Steelco	*Single-phase* 110V / 60Hz 220-240V / 50-60Hz *Three-phase* 200-230V /50-60Hz 380-480V / 50-60Hz	Up to 6100 W	From 1 to 4

Trade names:	Technical file:
EW 1, EW 1 S, EW 1 DUAL H	**DT-FT-18_M**

Hydrogen peroxide sterilizer PL line includes the following variants and names:

	FEEDING	POWER	DOORS NUMBER
Line: **PL** Trade Mark: Steelco	*Three-phase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Up to 5000 W	1 or 2

Trade names:	Technical file:
PL 70/1, PL 70/2, PL 130/1, PL 130/2, PL 40/1	**DT-FT-27_M**

2020-09-11

Hydrogen peroxide sterilizing agent SteelcoPro PL line includes the following variants and names:

	CONCENTRATION
Line: **SteelcoPro PL** Trade Mark:	58% of H_2O_2

Trade names: **SteelcoPro PL**	Technical file: **DT-FT-17_C**

Formaldehyde sterilizing agent SteelcoPro LTSF line includes the following variants and names:

	CONCENTRATION
Line: **SteelcoPro LTSF** Trade Mark:	From 10% to 20%

Trade names: **SteelcoPro LTSF 4; SteelcoPro LTSF 6; SteelcoPro LTSF 8**	Technical file: **DT-FT-13_C**

2020-09-11

Flusher Disinfectors / Bedpan washers for medical purpose PWD line includes the following variants and names:

	FEEDING	POWER	DOORS		BODY		SET UP
			NUMBER	MOVEMENT	WIDTH	HEIGTH	
Line: **PWD** Trade Mark: Miele	*Monofase* 110V / 60Hz 220-240V / 50-60Hz *Trifase* 200-230V / 50-60Hz 380-480V / 50-60Hz	Da 750W a 6900 W	1 o 2	MANUAL / SEMI-AUTOMATIC / AUTOMATIC	STANDARD / REDUCED / INCREASED	STANDARD / HIGH	STANDARD / E

Trade name:
PWD 8541 MD, PWD 8541 AD, PWD 8545 MD, PWD 8545 SAD, PWD 8545 AD, PWD 8546, PWD 8546 AD, PWD 8549, PWD 8543

Technical file:
DT-FT-01_M

Washer Disinfectors for medical purpose PWD line include the following variants and names:

	FEEDING	POWER	DOORS		BODY	SET UP
			NUMBER	MOVEMENT		
Line: **PWD** Trade Mark: Miele	*Single-phase* 110V / 60Hz 220-240V / 50-60Hz *Three-phase* 200-230V / 50-60Hz 380-480V / 50-60Hz	From 2220W to 37000W	1 OR 2	MANUAL / AUTOMATIC	STANDARD / HIGH	WITH DRYING / 3 or 4 DOSING PUMPS / WITH WATER SOFTNER

Trade name:
PWD 8531, PWD 8531 WS, PWD 8532, PWD 8532 WS, PWD 8534, PWD 8534 WS
PWD 6121, PWD 6122, PWD 6121 TH1, PWD 6122 TH1, PWD 6121 TH2, PWD 6122 TH2

Technical file:
DT-FT-04_M
DT-FT-03_M

2020-09-11

CERTIFICATO CE

Certificato n. 1879/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

STEELCO SPA

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

mantiene nello stabilimento di:

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

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

un sistema qualità che assicura la conformità dei seguenti prodotti:

Soluzione disinfettante per dispositivi medici invasivi

Mod. SteelcoXide-A, SteelcoXide-B e SteelcoXide-DT
Marca STEELCO

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:
DM16A0650339-01; DM17-0007338-01; DM19-0040534-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2016-05-16
Data aggiornamento:	2019-09-18
Sostituisce:	2017-02-02
Data scadenza:	2024-05-26

DocuSigned

IMQ

EC CERTIFICATE

Certificate No 1879/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

STEELCO SPA

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

manages in the factory of:

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

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

a quality assurance system ensuring the conformity of the following products:

Disinfectant solution for invasive medical devices

Type ref. SteelcoXide-A, SteelcoXide-B e SteelcoXide-DT

Trade mark STEELCO

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM16A0650339-01; DM17-0007338-01; DM19-0040534-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2016-05-16
Updated:	2019-09-18
Substitution Date:	2017-02-02
Expiry Date:	2024-05-26

IMQ

PENTAX MEDICAL

PENTAX Europe GmbH
Julius-Vosseler-Str. 104
22527 Hamburg · Germany
T: +49 (0)40 · 561 92 - 0
F: +49 (0)40 · 561 92 - 247
www.pentaxmedical.com

Monica Menin Ostani
International Endoscopy Sales and Marketing
Business Manager

Via Balegante, 27
31039 Riese Pio X (TV) –ITALY

Hamburg, 27 August 2013
Phone +49 (0)40 - 56 192 0 Fax +49 (0)40 - 56 247

Declaration of Compatibility between PENTAX Medical and Steelco Wash and Disinfector

Dear Mrs. Menin Ostani,

Hereby we declare that Pentax medical endoscopes are compatible with reprocessing in below mentioned Steelco Wash and Disinfector (WD) reprocessing machines and Drying Cabinets System according a Declaration of compatibility by Steelco

Endoscopes	Washer Disinfector	Result and Confirmation
VNL-J10 series: • VNL8-J10 • VNL11-J10 • VNL15-J10	can be • connected, • reprocessed • dried in **all** Steelco WDs & Drying Cabinets Systems	Pass Confirmation
EB-J10 series: • EB19-J10	can be • connected, • reprocessed • dried in **all** Steelco WDs & Drying Cabinets Systems	Pass Confirmation
EB19-j10U	can be • connected, • reprocessed • dried in **all** Steelco WDs & Drying Cabinets Systems	Pass Confirmation

Endoscopes	Washer Disinfector	Result and Confirmation
EC38-i10N • scope pilot system	can be • connected, • reprocessed • dried in **all** Steelco WDs & Drying Cabinets Systems	Pass Confirmation
ED34-i10T2	can be • connected, • reprocessed • dried in Steelco EW-Series (EW1, EW1S, EW2 G2, EW2 2S, EW2 3S) WDs with folw combination detergent and disinfection • SteelcoXide A+B+DT • Neodisher Septo Pac (disgned for Steelco) • Neodisher SC (disgned for Steelco)	Pass

Best regards

PENTAX Europe GmbH

Dr. Kai Wolter
General Manager Safety and Quality

Heidrun Groten-Schweitzer
Reprocessing & Infection Control

PENTAX Europe GmbH
Julius-Vosseler-Str. 104
22527 Hamburg · Germany
T. +49 (0)40 - 561 92 - 0
F. +49 (0)40 - 561 92 - 247
www.pentaxmedical.com

Hamburg, 30 July 2018

Monica Menin Ostani

International Endoscopy Sales
and Marketing Business Manager

Via Balegante, 27

31039 Riese Pio X (TV) –ITALY

Material compatibility with neodisher Septo PAC and neodisher endo® SEPT PAC

Dear Mrs. Menin Ostani,

This document provides information based upon PENTAX Medical testing results indicating that our endoscopes have material compatibility with the following reprocessing product:

This compatibility means that the materials which compose a scope have durability with the reprocessing product.

Product name, **Product type**	• neodisher Septo PAC, Disinfectant • neodisher endo SEPT PAC, Disinfectant
Manufacturer	DR. WEIGERT (www.drweigert.com)
Original requester of the compatibility	PENTAX Medical (Europe)

<table>
<tr><th>Item</th><th>Condition A</th><th>Condition B</th></tr>
<tr><td>Temperature of chemical</td><td>25 [℃]</td><td>35 [℃]</td></tr>
<tr><td>Dilution rate (Concentration) of chemical</td><td>10[mL/L]
(ca. 0.15 [%-PAA])</td><td>10[mL/L]
(ca. 0.15 [%-PAA])</td></tr>
<tr><td>Contact time (Soaking time) into chemical</td><td>10 [min/cycle]</td><td>5 [min/cycle]</td></tr>
<tr><td>Compatible cycle
• Colonoscope, Sigmoidoscope,
• Small bowel scope, Esophaoscope,
• Bronchoscope</td><td colspan="2">1 [year] or 300 [cycles], whichever is shorter</td></tr>
<tr><td>• Ultrasound GI Scope,</td><td colspan="2">1 [year] or 170 [cycles], whichever is shorter</td></tr>
<tr><td>• 70 series Gastroscope [1]
(Refer to Page 3/3)</td><td>1 [year] or 300 [cycles], whichever is shorter</td><td rowspan="2">1 [year] or 450 [cycles], whichever is shorter</td></tr>
<tr><td>• Non-70series Gastroscope</td><td>1 [year] or 450 [cycles], whichever is shorter</td></tr>
</table>

PENTAX MEDICAL

PENTAX Europe GmbH
Julius-Vosseler-Str. 104
22527 Hamburg · Germany
T. +49 (0)40 - 561 92 - 0
F. +49 (0)40 - 561 92 - 247
www.pentaxmedical.com

• **Duodenoscope**	1 [year] or 150 [cycles], whichever is shorter	
• **EBUS Endoscopes**	1 [year] or 250 [cycles], whichever is shorter	
• **ENT Endoscopes without lumen** [2] (Refer to Page 3/3)	1 [year] or *700*[cycles], whichever is shorter	1 [year] or *450* [cycles], whichever is shorter
• **ENT Endoscopes with lumen**	1 [year] or 250 [cycles], whichever is shorter	

Important Note:

1. The information written in this document is only for EMEA region.
2. The cleaning/disinfection/sterilization efficacy with the product is not evaluated so we cannot guarantee the efficacy of cleaning/disinfection/sterilization with the product.
3. In the region where the product is available, keep attention on the user's usage. If repair or damage related to the product is increasingly observed, take the proper process to report that situation and ask re-evaluation of the material compatibility for the product.

PENTAX Europe GmbH

Dr. Stephan Lunau

Regulatory Affairs Compliance Leader,
Infection QARA EMEA

Heidrun Groten-Schweitzer

Heidrun Groten-Schweitzer

Manager Reprocessing &
Control

HOYA CORPORATION PENTAX Lifecare Division
Medical Instrument SBU (PENTAX Medical)
1-1-110 Tsutsujigaoka, Akishima-shi
Tokyo 196-0012
Tel:(042)500-5831・Fax:(042)500-5839

The endoscopes that have the material compatibility with

Model Name
EB-1170K
EB-1530T3
EB-1570AK
EB-1570K
EB-1572K
EB-1575K
EB15-J10
EB-1830T3
EB-1970AK
EB-1970K
EB-1970TK
EB-1970UK
EB-1972K
EB-1975K
EB-1990i
EB19-J10
EB19-J10U
EC-2990Fi
EC-2990Li
EC-2990Mi
EC-3430L
EC-3430LK
EC-3440FK
EC-3470FK
EC-3470LK
EC-3485FK
EC-3485LK
EC-3490Fi
EC-3490FK
EC-3490Li
EC-3490LK
EC-3490Mi
EC-3490MK
EC-3490TFi
EC-3490TLi
EC-3490TMi
EC34-i10F
EC34-i10L
EC34-i10M
EC34-i10TF
EC34-i10TL
EC34-i10TM
EC-380FK2P
EC-380FKP
EC-380LKP
EC-380MK2P
EC-381FC
EC-3830L
EC-3830LK
EC-3830TL
EC-3830TLK
EC-3831F
EC-3831L

Model Name
EC-3831LK
EC-3840F
EC-3870CIFK
EC-3870CILK
EC-3870FK
EC-3870FK2
EC-3870LK
EC-3870LZK
EC-3870MK
EC-3870MK2
EC-3870TLK
EC-3872LK
EC-3872TLK
EC-3881LK
EC-3885FK
EC-3885FK2
EC-3885L
EC-3885LK
EC-3885MK2
EC-3890Fi
EC-3890Fi2
EC-3890FK
EC-3890FK2
EC-3890FZi
EC-3890Li
EC-3890LK
EC-3890LZi
EC-3890Mi
EC-3890Mi2
EC-3890MK
EC-3890MK2
EC-3890MZi
EC-3890TFK
EC-3890TLK
EC38-i10F
EC38-i10F2
EC38-i10L
EC38-i10M
EC38-i10M2
EC38-i10NF
EC38-i10NL
ECN-1530
ECY-150s
ECY-1530
ECY-1570K
ECY-1570K-J
ECY-1575K
ED-3230K
ED-3270K
ED-3280K
ED-3430K
ED-3430T
ED-3430TK

Model Name
ED-3440T
ED-3470TK
ED-3480TK
ED-3485T
ED-3490TK
ED34-i10T
ED34-i10T2
ED-3670TK
ED-3680TK
EE-1580K
EG-1540
EG-1580K[1]
EG-1690K
EG16-K10
EG-1840
EG-1870K[1]
EG-2470K[1]
EG-2490K
EG-271C
EG-2730K
EG-2731
EG-2770K[1]
EG-2790i
EG-2790K
EG27-i10
EG-290KP
EG-291C
EG-2930
EG-2930K
EG-2931
EG-2931K
EG-2940
EG-2940K
EG-2970K[1]
EG-2985[1]
EG-2985K[1]
EG-2990i
EG-2990K
EG-2990Zi
EG29-i10
EG29-i10N
EG-3270UK
EG-3430
EG-3430K
EG-3470K[1]
EG-3485K[1]
EG-3490K
EG34-i10
EG-3630U
EG-3630UR
EG-3670URK
EG-3830UT
EG-3870CIK[1]

Model Name
EG-3870TK[1]
EG-3870UTK
EG-3890TK
EH-1990STK
EHY-110s
ES-3830K
ES-3831K
ES-3870K
ES-3885K
FB-10V
FB-15BS
FB-15P
FB-15RBS
FB-15V
FB-18BS
FB-18P
FB-18RBS
FB-18V
FB-19TV
FB-8V
FC-38FV
FC-38FV2
FC-38FW
FC-38FW2
FC-38LV
FC-38LW
FCN-15X
FCP-9P
FCY-15P2
FCY-15RBS
FD-34V2
FD-34W
FG-15W
FG-16V
FG-24V
FG-24W
FG-29V
FG-29W
FG-34UX
FG-34W
FG-36UX
FHY-10RBS
FHY-15RBS
FI-10BS
FI-10P2
I-10RBS
FI-13BS
FI-13P
FI-13RBS
FI-16BS
FI-16RBS
FI-7BS
FI-7RBS

Model Name
FI-9BS
FI-9RBS
FNL-10RAP
FNL-10RBS [2]
FNL-10RP3 [2]
FNL-13RAP
FNL-15RP3
FNL-7RP3[2]
FP-7RBS
FP-7RBS2
FS-34V
FUR-9P
FUR-9RBS
VLS-1070STK [2]
VLS-1190STK [2]
VLS-1590STi [2]
VNL-100s[2]
VNL-1070STK [2]
VNL-110s[2]
VNL-110STs[2]
VNL-1130 [2]
VNL-1170K [2]
VNL-1171K [2]
VNL-1190STK [2]
VNL11-J10[2]
VNL-150s
VNL-1530T
VNL-1570STK
VNL-1590STi[2]
VNL15-J10
VNL8-J10[2]
VNL-90s[2]
VSB-2990i
VSB-3430K

*1: 70 series Gastroscope
*2: ENT Endos copes without lumen

PENTAX Europe GmbH
Julius-Vosseler-Str. 104
22527 Hamburg · Germany
T: +49 (0)40 · 561 92 - 0
F: +49 (0)40 · 561 92 - 247
www.pentaxmedical.com

Monica Menin Ostani
International Endoscopy Sales and Marketing
Business Manager

Via Balegante, 27
31039 Riese Pio X (TV) –ITALY

Hamburg, 30 July 2018

Declaration of Compatibility between PENTAX Medical and Steelco Washer and Disinfector

Dear Mrs. Menin Ostani,

Hereby we declare that Pentax medical endoscopes are compatible with reprocessing in below mentioned Steelco Wash and Disinfector (WD) reprocessing machines according a Declaration of compatibility by Steelco.

Endoscopes	Washer Disinfector	Result and Confirmation
Inagina Series (i10c): • EG29-i10c • EG34-i10c M/F/L • EG38-i10c M/F/L	can be • connected, • reprocessed • dried in **all** Steelco WDs Systems with the following adapter sets: • Steelco 9991499 Connectors set for series 90-PENTAX Instruments • Leakage test PENRAX adapter OE-29 supplied with the scope • Cleaning PENTAX adapter OE-C20 (water-jet-port) supplied with the scope	Pass Confirmation

Best regards

PENTAX Europe GmbH

Dr. Stephan Lunau
Regulatory Affairs Compliance Leader,
QARA EMEA

Heidrun Groten-Schweitzer
Manager Reprocessing & Infection Control

Tuesday, May 19, 2020

COMPATIBILITY DECLARATION LETTER

To whom it may concern,

Based on the declaration letter which issued by Fabio Zardini, President & CEO of STEELCO SPA on 15 May 2020.
We undersigned, Aohua Endoscopy Co., Ltd., with registered office in Aohua Endoscopy Building, No.66, Lane133, Guangzhong Road, Minhang District, Shanghai, China, 201100, hereby declare following compatibility between Aohua endoscope and Steelco systems:

- **VGT-Q30J Gastroscope** can be properly connected with Steelco systems EW1-EW1 S-EW2-EW2 2S-EW2 3 S-ED200 S- EPW100 S by using **Steelco connectors**:

Biopsy channel code 660538
Air channel code 660128
Channels separator code 660088
Suction channel code 660528
Air Water channel code 660116
Auxiliary Water Jet channel code 660089
Leak test original AOHUA connector has to be used

- **VGT-Q30J Gastroscope** can be properly connected with Steelco Drying Storage Cabinets models ED100-ED150-ED200-ED250 by using **Steelco connector kit: 99911466**

- **VRL-1T30 Bronchoscope** can be properly connected with Steelco systems EW1-EW1 S-EW2-EW2 2S-EW2 3 S-ED200 S- EPW100 S by using **Steelco connectors**:

Biopsy channel code 660538
Suction channel code 660510
Leak test original AOHUA connector has to be used

- **VRL-1T30 Bronchoscope** can be properly connected with Steelco Drying Storage Cabinets models ED100-ED150-ED200-ED250 by using **Steelco connector kit:9991658**

Yours sincerely

Jiang Suping 2020.5.19
Service Development Manager
Aohua Endoscopy Co., Ltd.

Add: Aohua Endoscopy Building, No.66, Lane133,Guangzhong Road, Minhang District, Shanghai, China
Tel: +86-21-6768-1018 Web: www.aohua.com

Steelco

Miele Group Member

AERs

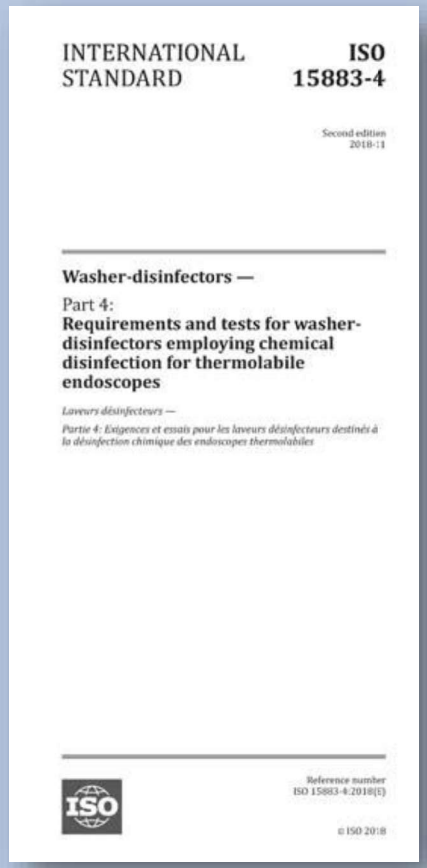
CLOSED SYSTEM REQUIREMENTS RATIONALE

RATIONALE

Main reasons why it's important to keep ISO 15883:4 compliance according with international and National Standard Requirements, Guidelines, Manufaturer Technical Features and Safety Rules:

1. ISO 15883-4 validation
2. Level 2 Script of the wfhss (World Federation for Hospital Sterilization Science) education group Reprocessing Endoscopes
3. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018
4. Legal implications linked to the Endoscopy Department Risk Management
5. Infections & MDRs
6. Patient Safety

RATIONALE 1



INTERNATIONAL STANDARD **ISO 15883-4**

Second edition
2018-11

Washer-disinfectors —

Part 4:
Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

Laveurs désinfecteurs —

Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles

Reference number
ISO 15883-4:2018(E)

© ISO 2018

ISO 15883-4 REQUIREMENTS

RATIONALE 1

ISO/FDIS 15883-4:2018(E) requirements:

Clause 8 Information to be supplied by the manufacturer

n) the detergent(s) and disinfectant(s) type tested with the WD, (see 4.3.3 and 4.4.5);

RATIONALE 1

ISO/FDIS 15883-4:2018(E)

ANNEX A

A.2 Before installation of the WD

It is expected that the WD manufacturer will:

— state with which endoscopes the WD can be used;

— provide test data demonstrating the performance of the WD with respect to both cleaning and disinfection using process chemicals specified by the WD manufacturer; this is to be done in the light of information provided by the process chemical manufacturer;

ANNEX 3

A.3 Installation and operation of the WD

It is the responsibility of the purchaser/user facility to ensure that the WD is installed and operated correctly.

The responsibility for ensuring that the WD is correctly installed and functions correctly usually falls to the purchaser/user.

This includes:

— performance qualification tests;

— use of the recommended process chemicals;

RATIONALE 1

A full ISO Validation means a Technical Dossier made of 20 Type Test provided by the manufacturer (on top of this the manufacturer has to guarantee full compatibility of machine components with chemicals and chemicals compatibility with endoscopes). Type test must be performed by an independent certified Microbiological LAB.

A PQ (performance Qualification) enclose **8 recomended test** and it's not to be intended as a full compliance with ISO 15883:4.

Table C.2 — Summary of tests in addition to ISO 15883-1:2006+Amd 1:2014

Brief description of test	Requirement subclause	Test sub-clause	Type test	Works test	Operational qualification test	Performance qualification test	Routine[a] test
1. Leak test failure alarm	4.2.3	6.5.3.3	X	X	X	B	X (Q)
2. Leak test non-connection test	4.2.4 4.2.5	6.5.3.4	X	X	B	X	~~B~~ X(Q)
3. Leak test over-pressurization prevention test	4.2.4 d)	6.5.3.2	X	X	B	B	B
4. Cleaning efficacy	4.3.5	6.11	X	B	X	X	X (Q)
5. *in vitro* disinfectant efficacy	4.4.2.2	6.12.2	X	B	B	B	B
6. Disinfection efficacy — Type test	4.4.2.5	6.12.6.1	X	B	B	B	B
7. Complete process — Operational and performance qualification	4.1.3	6.12.6.2 6.12.6.3	O O	B B	X B	O X	X X (Q)
8. Drying	4.7	6.8	X	O	X	B	X
9. Disinfection of liquid transport system — Type test	4.8.5	6.12.5.1	X	B	B	B	B
10. Disinfection of liquid transport system — Operational qualification and routine test	4.8.5	6.12.5.2	O	B	X	B	X
11. Self-disinfection test — Type test	4.8.7	6.12.3.1	X	B	B	B	B
12. Self-disinfection test — Operational qualification and routine test	4.8.7	6.12.3.2	O	B	X	B	X
13. Disinfection of water treatment equipment	4.9.2	6.12.4.1	X	B	O	B	B
14. Final rinse water treatment — Microbial quality	4.5.2	6.12.4.2	O	B	X	B	B
15. Channels non-obstruction test	5.2.2.1	6.6	X	X	B	X	X(Q)
16. Channels non-connection test	5.2.2.2	6.7	X	X	B	X	X (Q)

X – Recommended

B – Not recommended

O – Optional

Q – Quarterly, W – Weekly

[a] Frequency of routine testing may be established based on risk assessment using trend analysis.

Table C.2 *(continued)*

Brief description of test	Requirement subclause	Test sub-clause	Type test	Works test	Operational qualification test	Performance qualification test	Routine[a] test
17. Temperature throughout process	4.4.3 5.4.2 5.4.3	6.9	X	X	X	X	X (Q)
18. Minimum process temperature test	5.4.4	6.9.2	X	X	X	X	X (Q)
19. Water quality	4.5.2 4.9.2.3 a) 4.9.2.3 b)	6.3	B	B	X	X	X (W) X (Q)
20. Chemical dosing test (single-dose container)	5.7	6.10	X	X	X	B	O

X – Recommended

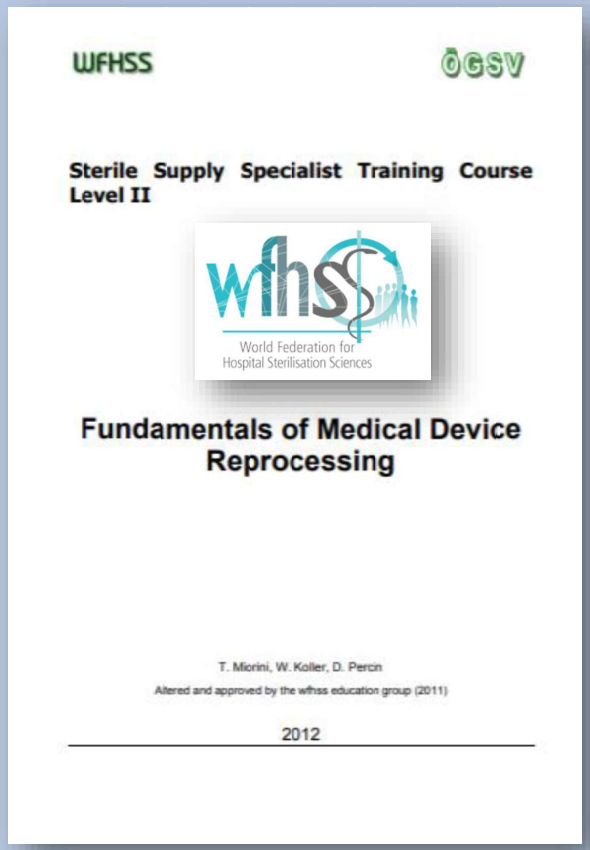
B – Not recommended

O – Optional

Q – Quarterly, W – Weekly

[a] Frequency of routine testing may be established based on risk assessment using trend analysis.

RATIONALE 2



LEVEL 2 SCRIPT OF THE World Federation Hospitals Sterilisation Science EDUCATION GROUP REPROCESSING ENDOSCOPES

RATIONALE 2

The WFHSS dedicates itself to the promotion of the worldwide harmonization of sterilization departments and of decontamination practices especially by providing:

1. a meeting place for national and regional non-profit sterilization societies, thus stimulating cooperation and the exchange of information and best practices;
2. information via its website to all our stakeholders and interested parties.

RATIONALE 2

In the **Level 2 Script of the wfhss education group Reprocessing Endoscopes** is stated the following:

Compatibility of the chemical substances used for reprocessing (i.e. compatible detergent and disinfectant) is an important factor for successful reprocessing. If incompatible substances are used together, this can give rise to massive chemical reactions (e.g. white deposits on the endoscope). Ask the supplier to give a written confirmation of safety and compatibility!

There is a European (and international) standard (EN ISO 15883-4) regulating endoscope washer-disinfectors, which sets out the requirements for an EWD as well as its performance criteria.

The above statement shows that the ISO 15883-4 compliance means the use of certified and validated chemistries by the AER manufacturer.

RATIONALE 3

Position Statement

Thieme

Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018

ESGE ESGENA

Authors

Ulrike Beilenhoff[1], Holger Biering[2], Reinhard Blum[3], Jadranka Brljak[4], Monica Cimbro[5], Jean-Marc Dumonceau[6], Cesare Hassan[7], Michael Jung[8], Birgit Kampf[9], Christiane Neumann[9], Michael Pietsch[10], Lionel Pineau[11], Thierry Ponchon[12], Stanislav Rejchrt[13], Jean-François Rey[14], Verona Schmidt[15], Jayne Tillett[16], Jeanin E. van Hooft[17]

Institutions

1 ESGENA Scientific Secretary, Ulm, Germany
2 Grevenbroich, Germany
3 Olympus Europa, Hamburg, Germany
4 University Hospital KBC-Zagreb-Rebro, Zagreb, Croatia
5 Medical Devices Division, CBC Europe Srl, Nova Milanese (MB), Italy
6 Cedyt Endoscopy Center, Buenos Aires, Argentina
7 Digestive Endoscopy Unit, Catholic University, Rome, Italy
8 2nd Department of Internal Medicine, Katholisches Klinikum, Mainz, Germany
9 ESGENA Past President, Birmingham, UK
10 Department of Hygiene and Infection Prevention, Medical Center, University Hospital, Mainz, Germany
11 Biotech Germande, Marseille, France
12 Digestive Diseases Department, Hôpital Edouard Herriot, Lyon, France
13 2nd Department of Internal Medicine, Charles University Teaching Hospital, Hradec Králové, Czech Republic
14 Institut Arnault Tzanck, St. Laurent du Var, France
15 Microbiology and Hygiene Department, Cheminche Fabrik Dr. Weigert, Hamburg, Germany
16 St. Woolos Hospital, Newport, UK
17 Department of Gastroenterology and Hepatology, Amsterdam University Medical Centers, University of Amsterdam, The Netherlands

Bibliography

DOI https://doi.org/10.1055/a-0759-1629
Published online: 20.11.2018 | Endoscopy 2018; 50: 1205–1234

ISSN 0013-726X

Corresponding author

Ulrike Beilenhoff, ESGENA Scientific Secretariat, Ferdinand-Sauerbruch-Weg 16, 89075 Ulm, Germany
info@esgena.org

ABSTRACT

This Position Statement from the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology Nurses and Associates (ESGENA) sets standards for the reprocessing of flexible endoscopes and endoscopic devices used in gastroenterology. An expert working group of gastroenterologists, endoscopy nurses, chemists, microbiologists, and industry representatives provides updated recommendations on all aspects of reprocessing in order to maintain hygiene and infection control.

REPROCESSING OF FLEXIBLE ENDOSCOPES AND ENDOSCOPIC ACCESSORIES USED IN GASTROINTESTINAL ENDOSCOPY:

POSITION STATEMENT OF THE EUROPEAN SOCIETY OF GASTROINTESTINAL ENDOSCOPY (ESGE) AND EUROPEAN SOCIETY OF GASTROENTEROLOGY NURSES AND ASSOCIATES (ESGENA) – UPDATE 2018

RATIONALE 3

All Steelco AERs are fully compliant to EN ISO 15883:4 standard.

Certifications have been released by European Certified Labs:

20/30 Labs

HYGCEN GERMANY

BIOTECH·GERMANDE

RECOMMENDATION

EWDs compliant with EN ISO 15883 standard series should be the first choice for endoscope cleaning and disinfection, in order to:

- Provide a standardized and validated reprocessing cycle in a closed environment;
- Document the process steps automatically (via a printer or electronically);
- Provide reliable and reproducible reprocessing;
- Minimize staff contact with chemicals and contaminated equipment;
- Minimize contamination of the environment;
- Facilitate the work involved for personnel;
- Lower the risk of damage to endoscopes

PROCESS VALIDATED

RATIONALE 4

LEGAL IMPLICATIONS
LINKED TO THE ENDOSCOPY DEPARTMENT
RISK MANAGEMENT

RATIONALE 4

Risk Management/Legal issues

Patients **claims against physicians and health institutions** are increasing and becoming a serious problem in health economy.

Strategies for decreasing these claims and reducing financial losses are an important part of every health plan.

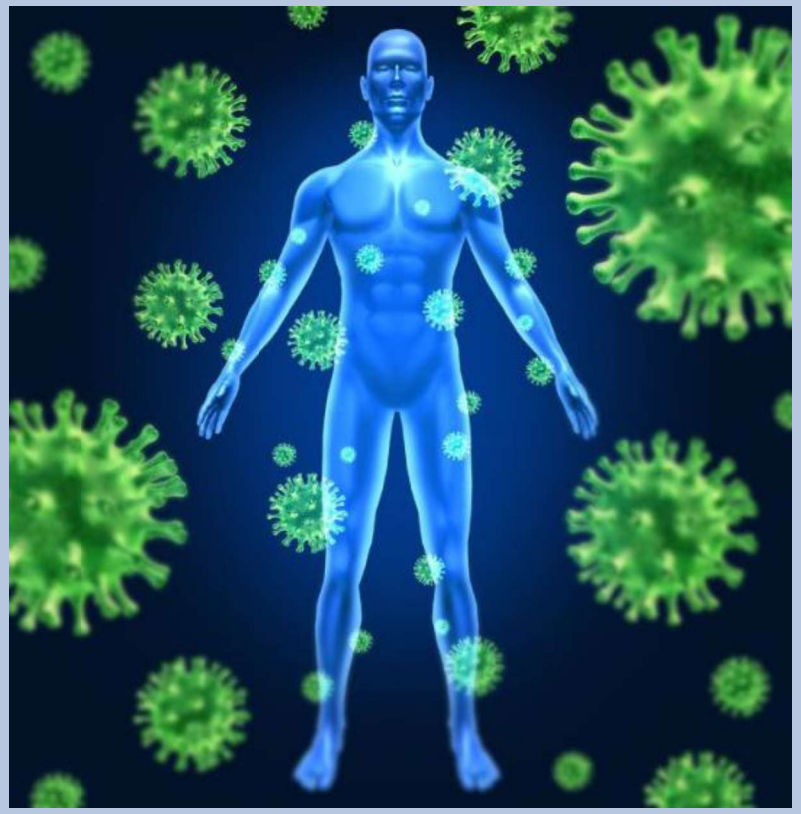
Reporting adverse events, complications and fulfilling protocols, guidelines, standards and norms should be an integral part of daily routine daily work in gastroenterology units and endoscopy departments.

Being prepared in case of patients potential claims is important for several reasons:

- To prove that all the endoscopes reprocessing procedures have been put in place according with the most recent protocols, standard, guidelines, norms and are fully traced & documented
- To prove that all the reprocessing devices have been installed, served and used according to manufacturer instructions *(use of approved & validated chemistry is part of it) → IQ, OQ, PQ*
- To prove endoscope compatibility with the chemistry in use, with the AER and connectors and when possible demonstrate the safer traceability of the chemistry by the AER by the adoption of RFID labels able to read batch number, exipiration date and residual quantity to run cycles

RATIONALE 5

INFECTIONS & MDRS



RATIONAL 5

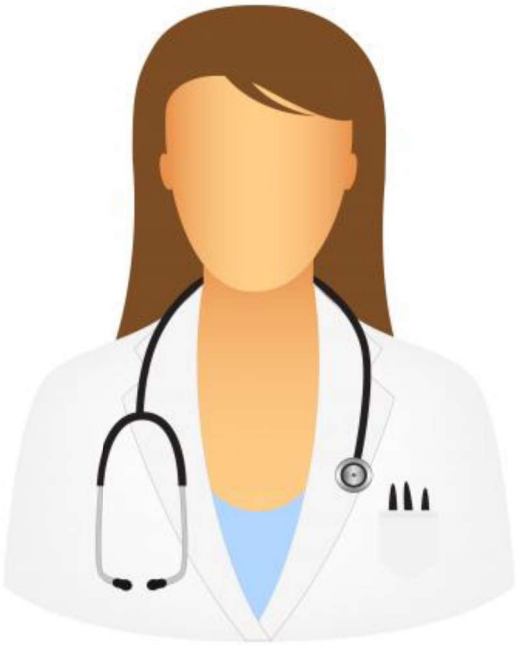
Prevention of multidrug resistant infections from contaminated duodenoscopes Position Statement of ESGENA

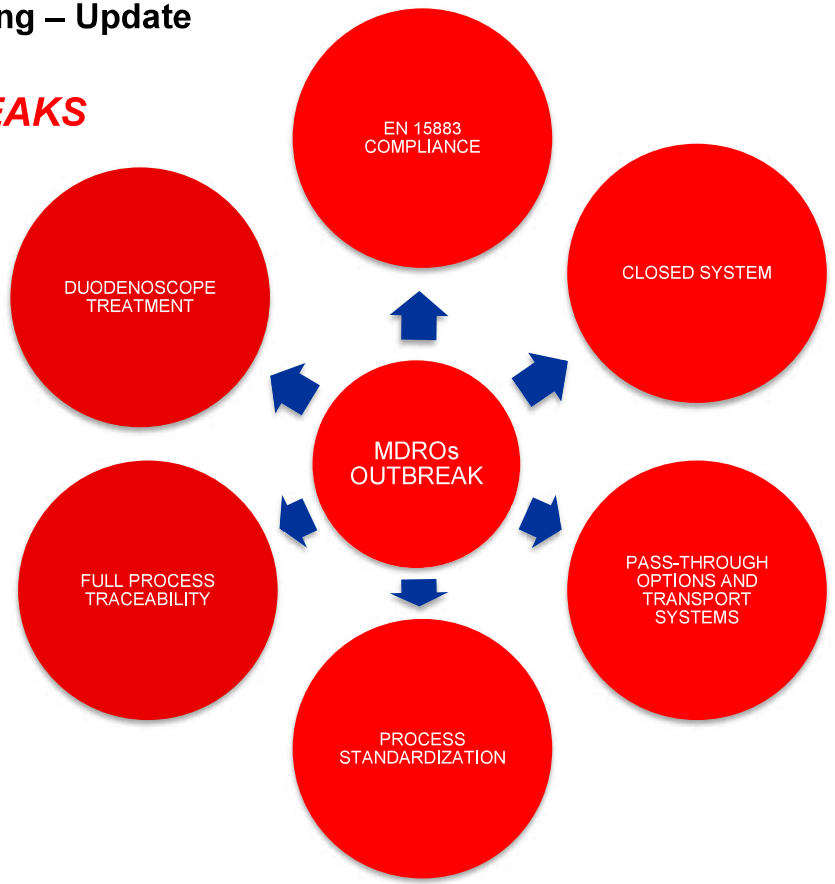
Safe and effective endoscope reprocessing is crucial to patient safety in endoscopy. Noncompliance with guidelines as well as deviations from standardized and validated reprocessing protocols may lead to ineffective reprocessing, with the possibility of patient-to-patient transmission. Recent MDRO outbreaks show how narrow the margin of safety is, despite compliance with reprocessing protocols.

RATIONAL 5

ESGENA Position Statement on Endoscopes Reprocessing – Update 2018:

HOW TO FIGHT AGAINST MDROS OUTBREAKS





RATIONALE 6

PATIENT SAFETY

RATIONALE 6

Patients Safety & Nurses Piece of mind means that:

- Every gastroenterology unit should adopt quality indicators and quality improvement plans for advancing patient safety.

- Endoscopy staff is responsible for individual, comprehensive patient care, technical assistance including reprocessing, documentation and management of endoscopy units.

Why?:

- Several studies reported a lack of compliance with established guidelines for endoscope reprocessing.

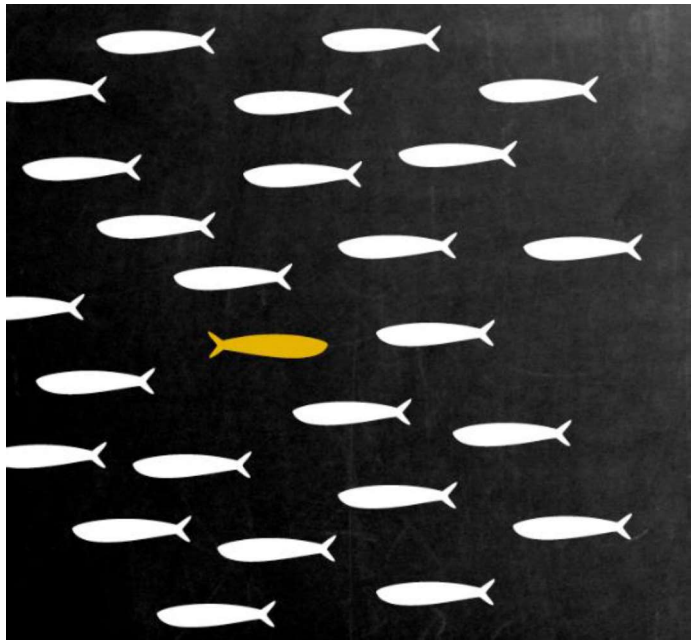
An increased risk of infection transmission has been associated with:

- endoscope and AER use
- human error
- inadequate or delayed reprocessing
- failure to sterilize accessory equipment
- incorrect selection of disinfectants
- improper drying

Steelco Miele Group Member

Question ourselves then …

Why should we take the risk to «swim against the tide»?



Steelco

Miele Group Member

THANK YOU
for your
ATTENTION!

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

CE 0051

Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
The undersigned, officer of the under-written company, hereby declares that the product:
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:

Nome/Modello:
Name/Type:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
SteelcoXide-A

N° di Serie/Lotto:
Serial/Lot N.:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
19XXXXXXXXXX

[GMDN: 44835]

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 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.1879/MDD con validità fino al **26/05/2024.**

.

*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 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.1879/MDD valid till **2024/05/26**.*

.

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.
Cette déclaration 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.1879/MDD avec validité jusqu'à **26/05/2024.**

.

*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.*
Diese Erklärung bestätigt auch die Konformität zu 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 1879/MDD, gültig bis zum **26/05/2024**, bestätigt wird..*

.

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 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.1879/MDD con validez hasta a **26/05/2024.**

.

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

RIESE PIO X, 20 / 09 / 2019

Direttore Generale
Managing Director
Director Général
Geschäftsführer
Gerente

Fabio Zardini
Steelco S.p.A.

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

CE 0051

Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
The undersigned, officer of the under-written company, hereby declares that the product:
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:

Nome/Modello:
Name/Type:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
SteelcoXide-B

N° di Serie/Lotto:
Serial/Lot N.:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
19XXXXXXXXXX

[GMDN: 44835]

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 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.1879/MDD con validità fino al **26/05/2024.**

.

*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 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.1879/MDD valid till **2024/05/26**.*

.

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.
Cette déclaration 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.1879/MDD avec validité jusqu'à **26/05/2024.**

.

*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.*
Diese Erklärung bestätigt auch die Konformität zu 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 1879/MDD, gültig bis zum **26/05/2024**, bestätigt wird..*

.

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 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.1879/MDD con validez hasta a **26/05/2024.**

.

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

RIESE PIO X, 20 / 09 / 2019

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

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

CE 0051

Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:
The undersigned, officer of the under-written company, hereby declares that the product:
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:

Nome/Modello:
Name/Type:
Nom/Modèle:
Name/Model:
Nombre/Modelo:
SteelcoXide-DT

N° di Serie/Lotto:
Serial/Lot N.:
N° de Série/Lot :
Serial N./ Reihe-Zahl:
N° de Serie/Lote:
19XXXXXXXXXX

[GMDN: 44835]

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 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.1879/MDD con validità fino al **26/05/2024.**

.

*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 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.1879/MDD valid till **2024/05/26**.*

.

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.
Cette déclaration 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.1879/MDD avec validité jusqu'à **26/05/2024.**

.

*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.*
Diese Erklärung bestätigt auch die Konformität zu 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 1879/MDD, gültig bis zum **26/05/2024**, bestätigt wird..*

.

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 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.1879/MDD con validez hasta a **26/05/2024.**

.

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

RIESE PIO X, 20 / 09 / 2019

Direttore Generale
Managing Director
Director Général
Geschäftsführer
Gerente

Fabio Zardini
Steelco S.p.A.

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ

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:

Name/Type:
Nome/Modello: **EW 1**

Serial/Lot N.:
N° di Serie/Lotto: **XXXXXXXXXX**

[GMDN:36253]

[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 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. 909/MDD valid till **26/05/2024**.

[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 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. 909/MDD con validità fino al **26/05/2024**.

Applied directives:
Direttive applicate:

93/42/EEC (Medical Devices Directive) + 2007/47/EC
2011/65/EU (RoHS Directive)

RIESE PIO X , 07/02/2022

Managing Director
Direttore Generale

Fabio Zardini
Steelco S.p.A.

Via Balegante, 27
31039 Riese Pio X (TV)
ITALIA – ITALY – ITALIE - ITALIEN
Tel. +39 0423 7561 Fax +39 0423 755528
info@steelcogroup.com www.steelcogroup.com

Steelco Miele Group Member

EU DECLARATION OF CONFORMITY
DICHIARAZIONE UE DI CONFORMITÁ
DÉCLARATION DE CONFORMITÉ UE

CE

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:

Name/Type: *Nome/Modello:* Nom/Modèle:	**ED 150/1**	LOT	---
REF	**999XXXXX**	SN	**XXXXXXXXXXXX**
Basic UDI-DI: *UDI-DI di base:* IUD-ID de base:	**8051520EDXXY3**	**GMDN**	**45635**

[EN] Referring to Regulation (EU) 2017/745 (hereinafter the "MDR"), is classified on **I** class, according to rule 13 of the annex VIII, designed and manufactured in conformity with the general requirements of safety and performance of annex I, applying the provisions of the harmonized standards.
This declaration is of conformity is issued under the sole responsibility of the manufacturer.
The juridical person authorized to compile the technical documentation is Steelco S.p.A.
.

[IT] In riferimento al Regolamento (UE) 2017/745 (di seguito come "MDR"), è classificato in classe **I**, in accordo alla regola 13 dell'allegato VIII, è stato progettato e costruito in conformità ai requisiti generali di sicurezza e prestazione dell'allegato **I**, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante.
La persona giuridica autorizzata a costituire la documentazione tecnica è Steelco S.p.A.
.

[FR] En référence au Règlement (UE) 2017/745 (ci-après **l**e "MDR"), est classifiée en classe **I**, en accord à la règle 13 annexe VIII, a été projetée et construit en conformité aux les exigences générales en matière de sécurité et de performances de l'annexe I, appliquant les dispositions des normes harmonisées.
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.
La personne juridique autorisée à constituer la documentation technique est Steelco S.p.A.
.
.

Applied regulations:
Regolamenti applicati:
Règlements appliqués:

- **2017/745/EU (Medical Devices Regulation)**
- **2011/65/EU (RoHS 2 Directive)**

Refers to the Annex for the applied standards.
Le norme applicate sono indicate in allegato.
Les normes appliquées sont indiquées en annexe.

RIESE PIO X, 14 / 02 / 2021

Chairman of the BOD & Chief Executive Officer
Presidente del CDA e Amministratore Delegato
Président du CDA et Director Général

Fabio Zardini
Steelco S.p.A.

ANNEX
ALLEGATO
ANNEXE

Name/Type:
Nome/Modello: **ED 150/1**
Nom/Modèle:

LOT **---**

REF **999XXXXX**

SN **XXXXXXXXXXXX**

Applied standards:
Norme applicate:
Normes appliqués:

- **EN 61010-1:2010 + A1:2014**
- **EN ISO 14971:2019**
- **EN 61326-1:2013**
- **EN 62304:2006 + A1:2015**
- **EN 62366:2015**
- **EN 16442:2015**

FUJIFILM
Value from Innovation

Konformitätserklärung
Declaration of Conformity

Im Sinne der FUJIFILM Europe GmbH Richtlinie zur Materialkompatibilität
according to the FUJIFILM Europe GmbH directive of material compatibility

Name und Anschrift des Herstellers
Name and address of the manufacturer:

ggf. Name und Anschrift seines in der EU niedergelassenen Bevollmächtigten
Where appropriate his authorised representative in EU:

Steelco S.p.A. (Miele Group Member)
Via Balegante, 27 - 31039 Riese Pio X (TV) – ITALY

Diese Erklärung bezieht sich nur auf das original Produkt, wenn alle Anleitungen des Herstellers befolgt werden. Die zu beachtenden Richtlinien gemäß Produktbeschriftung dieses Biozids beinhalten die Beachtung der Anwendungsparameter. FUJIFILM kann die Kompatibilität nicht versprechen, wenn diese Empfehlungen nicht befolgt werden und/oder die Gebrauchsanweisungen des Herstellers oder die chemische Formel geändert werden.
This declaration relates exclusively to the original product if all manufacturer's instructions are followed. Adherence to the germicide's product labeling includes compliance with the disinfectant's exposure parameters, etc. FUJIFILM cannot ensure compatibility if these recommendations are not followed and/or if manufacturer's usage instructions or chemical formulation are changed.

Hiermit erklären wir, dass das nachstehende Product
Herewith we declare, that the machinery described below

Produktbezeichnung / *product denomination*:

SteelcoXide A+B; SteelcoXide DT;

allen einschlägigen Bestimmungen der FUJIFILM Europe GmbH Richtlinie zur Materialkompatibilität zur Endoskopserie 700 entspricht.
is complying with all essential requirements of the FUJIFILM Europe GmbH directive according to the material compatibility for 700 series endoscopes.

Bezugsquelle /Bericht
Approval reference

FEGEXE1116-HygMaG7/T044

Bevollmächtigter für die Zusammenstellung der relevanten technischen Unterlagen
The person authorised to compile the relevant technical documentation

Frank Sauer / EXE-Service Support Group
FUJIFILM Europe GmbH

Stempel / stamp
FUJIFILM Europe GmbH
Heesenstraße 31
40549 Düsseldorf

Ort, Datum *Place, Date*	Name, Vorname und Funktion des Unterzeichners *surname, first name and function of signatory*	Unterschrift *Signature*
Willich, 05.02.2018	**Haruhiko Arai / FEG Service Manager Quality**	

FUJIFILM

FUJIFILM ITALIA S.p.A.

S.S. n° 11 Padana Superiore, 2/B
20063 Cernusco sul Naviglio (MI) - Italy
Tel. 02.92974.1 - Fax 02.92974.591
http:\\www.fujifilm.it - info@fujifilm.it

TO WHOM IT MAY CONCERN

Cernusco Sul Naviglio, June 23rd, 2016
Prot. n° **33761**/2016/GV/dm

The undersigned Giovanni Ettore Valtorta, born in Sovico (MB) – Italy – on January 31st, 1959 and living in Sovico (MB) – Italy – Via San Francesco d'Assisi, 8 in his capacity as Special Attorney of FUJIFILM Italia S.p.A., having its register office in Cernusco sul Naviglio (MI) – Italy – S.S. n° 11 Padana Superiore, 2/b – Fiscal Code 09435590154, VAT n° 11025740157, under his responsibility,

DECLARES

That FUJIFILM endoscopes are fully compatible with Steelco AERs series EW.

Your successfully.

FUJIFILM Italia S.p.A.
A Special Attorney
Giovanni Ettore Valtorta

VALTORTA
GIOVANNI ETTORE
31/01/1959
4 1 A 1959
SOVICO MI
ITALIANA
SOVICO
VIA SAN FRANCESCO D'ASSISI 8

DIRIGENTE

A
182
BRIZZOLATI
VERDI
NESSUNO

Firma del titolare

SOVICO 21/01/2015

IL SINDACO

SCADENZA 31/01/2025

Diritti E. 5,42

AV 0997721

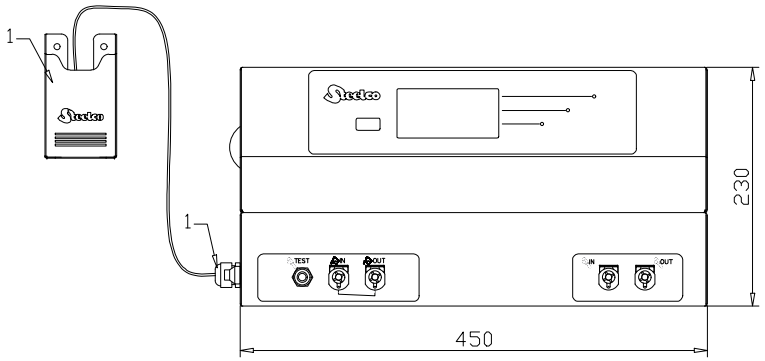
REPUBBLICA ITALIANA

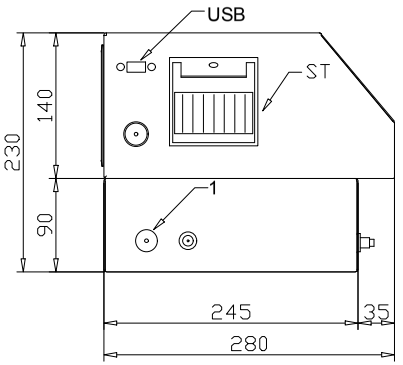
COMUNE DI
SOVICO (MB)

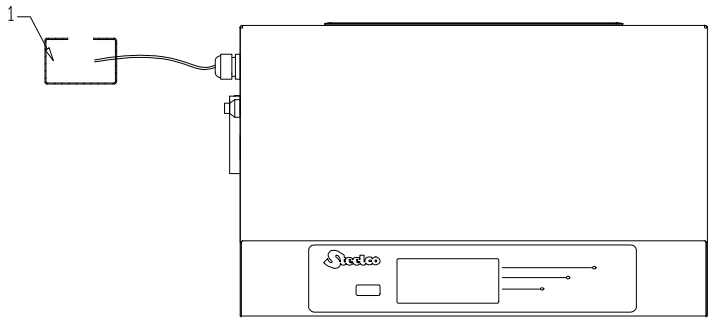
CARTA D'IDENTITÀ

N° AV 0997721

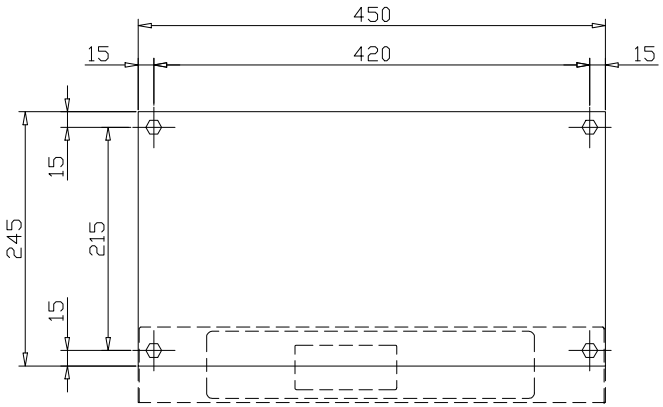
DI
VALTORTA
GIOVANNI ETTORE







FEET POSITION



SPECIFICA CONNESSIONI - CONNECTION DETAILS	
1. ELETTRICA - ELECTRICAL	
Tensione - Voltage:	230-240V / 1~+N+PE / 50Hz
Potenza - Power:	250W / 1,5 A
Fusibili - Fuse rating:	1 x 2 A
Cavo e sezione min. - Cable and min. section:	3 x 1,5 mm²
Colori dei cavi - Cable colours:	
N: Blu - Blue PE: Giallo/Verde - Yellow/Green L1: Marrone - Brown	

PESI - WEIGHTS	
Netto totale - Total Net:	13 daN (kg)

ALTRE SPECIFICHE - OTHERS DETAILS	
AMBIENTE - ENVIRONMENT	
Temperatura -Temperature:	+5...+40°C (+41...+104°F)
Umidità relativa - Relative humidity:	Max 80%(5...31°C); 50% (40°C)
Liv. pr. sonora - Eq. noise pr. lev. (Leq)	< 70 dB(A)

CONFIGURAZIONE - CONFIGURATION	
A) Risc. in circolazione-Circulating heating type:	E: ELETTRICO-ELECTRICAL
B) Risc. in asciugatura-Air drying heating type:	X: N.A.
C) Risc. in taniche-Tanks water heating type:	X: N.A.

ACCESSORI INSTALLATI - INSTALLED OPTIONALS

ST) Stampante - Printer

NOTE - NOTES

- La macchina deve essere livellata orizzontalmente.
- L'alimentazione elettrica di ogni macchina deve essere protetta con un interruttore differenziale (30 mA, tipo "AC").
- Tutte le connessioni dei servizi per la macchina devono rispettare tutte le normative e pratiche locali applicabili.
- Il fabbricante si riserva il diritto di apportare modifiche al prodotto che possono non essere riportate nel disegno.

- The machine shall be horizontally levelled.
- The electrical supply of each machine must be protected with a ground fault interrupter (30 mA, "AC" type).
- All services connections to the machine must comply with all applicable local codes and practices.
- The manufacturer reserves the right to make product changes that may not be reported in the drawing.

Rev.	Data / Date	Descrizione / Description	Dis./Drawn	Approv.
0.5	22-11-2018	AGGIORNATE CONNESSIONI LATERALI - UPDATED LATERAL CONNECTIONS	Iordan C.	Capovilla I.

THESE DRAWINGS ARE:

☐ FOR APPROVAL ☐ FOR INFORMATION ONLY ■ AS BUILT ☐ DRAFT

FORMAT: A3 | MOD.: MD04#42 Rev.13

Descrizione/Description: DISPOSIZIONE GENERALE / GENERAL ARRANGEMENT

N° documento / Document n° : GA_XXXXXXXXXX

Foglio/Sheet: 1 / 1

Modello / Model: EPW100 (250W 230-240V 50Hz - EXX version - ST)

Data / Date: 26/01/2017 | Rev. / Rev.: 0.5 | Scala / Scale: 1:5

Codice cliente / Customer code:	Progetto / Project:	Ingegneria / Engineering:	Rif. ordine / Order ref.:	N° di serie / Serial n°:
..	--	STEELCO	--	--

FUJIFILM
Value from Innovation

FUJIFILM Europe GmbH

Heesenstraße 31, 40549 Düsseldorf,
PO Box 270131, 40524 Düsseldorf, Germany
Phone +49 211 5089-100, Fax +49 211 5089-344
http://www.fujifilm.eu

Willich, 23.07.2018

To Whom it may concern

Herewith we confirm, that based on the test results of the company Steelco and the submitted report from the 20.06.2018, the use of the FUJIFILM series ED-580XT in reprocessing machines made by Steelco, is basically permitted and no problems are to be expected.

Haruhiko Arai
Manager Quality & Service Support

AZIENDA OSPEDALIERA UNIVERSITARIA INTEGRATA
VERONA
(D.Lgs. n. 517/1999 - Art. 3 L.R.Veneto n. 18/2009)

U.O. Clinica di Gastroenterologia - *Direttore Prof. Luca Frulloni*

U.O. Semplice Organizzata di Endoscopia Digestiva

Responsabile: Dr. Armando Gabbrielli

Policlinico G.B. Rossi, P.le L.A. Scuro, 10 - 37134 Verona - Tel. 045 8124743 - Fax 045 8124898

e-mail: endoscopia.digestiva.op@azosp.vr.it

Date 22.6.2016

We are glad to communicate that, in our GI Departement – AOUI of Verona - Steelco S.p.A AERs Systems (EW) installed in 2012 are succesfully used with Olympus endoscopes series 140, 160 and 180.

Sincerly

Armando Gabbrielli, M.D.

AZIENDA OSPEDALIERA UNIVERSITARIA INTEGRATA DI VERONA
OSPEDALE POLICLINICO "BORGO ROMA"
U.O.C di Gastroenterologia
Unità Organizzativa Semplice
ENDOSCOPIA DIGESTIVA
DOTT. ARMANDO GABBRIELLI
ROMA 32818

CASA DI CURA VILLA IGEA S.p.A.
STRADA MOIRANO 2 – 15011 ACQUI TERME (AL) ITALY tel. +39,0144-310801 fax +39,0144-310829
E-mail: info@villaigea.com
c.f. e P.IVA 02035510060 Numero REA: AL-220838 CAP. SOC. I.V. € 1.700.000,00

Acqui Terme, June 23th, 2016

We are glad to comunicate that, in our Ambulatory Department identified as "Endoscopia Digestiva" located in Casa di Cura Villa Igea S.p.A., the Firm SO.E.M. sold and installed in 2014 and 2015 two Systems EW1 of Steelco production.
Both systems are successfully used with Olympus endoscopes series 180 and 190.

Best regards

The Legal Representative

Casa di Cura "Villa Igea" S.p.A.
Il Consigliere Delegato
Poggio Dott. Giovanni

The Bioingeenering Dept.
Maurizio La Gamba

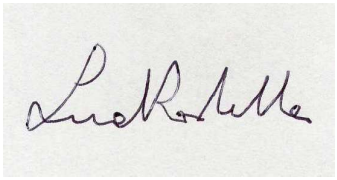
AZIENDA OSPEDALIERA DI VERONA - OSPEDALE CIVILE MAGGIORE
SERVIZIO DI CHIRURGIA ENDOSCOPICA
Responsabile: Dott. Luca Rodella

Verona, June 23, 2016

We are glad to communicate that, in our GI Department – Piastra Endoscopica / Endoscopy Dept at Polo Chirurgico "P. Confortini" - Maggiore Hospital of Verona - Steelco S.p.A AERs Systems (EW) installed in 2011 are succesfully used with Olympus endoscopes series 180 and 190.

Sincerely

Luca Rodella
Head Endoscopy Unit



Servizio Sanitario Nazionale - Regione Veneto
AZIENDA UNITA' LOCALE SOCIO-SANITARIA N. 13
DIPARTIMENTO INTERNISTICO OSPEDALE DI DOLO
U.O.S. di GASTROENTEROLOGIA ed ENDOSCOPIA DIGESTIVA
Resp. **Dr. Renato Marin**

Dolo, 13.07.2016

U.O.S. di Gastroenterologia ed Endoscopia Digestiva

Dr. Renato Marin
(Responsabile)

Medici

Dr.ssa Erica Cervellin
Dr. ssa Sara Antoniazzi
Dr. ssa Adriana Sergio

Infermieri

I.P. Mara Celin
(con ruolo di coordinamento)
I.P. Silvia Bizzotto
I.P. Federica Carlesso
I.P. Federico Cipriotto
I.P. Samuele Marcato
I.P. Lisa Morelli
I.P. Grazia Salmaso
I.P. Lisa Scantamburlo

O.S.S.

Sig.ra Elisabetta Zara

Telefoni

Sala A / Segreteria
041 5133423
Sala B (tel. e fax)
041 5133460

e-mail:

endoscopiadigestiva.dolo@ulss13mirano.ven.it

Prenotazione prestazioni:

CUP: tel. 041 5103520

Prestazioni erogate

- EGDS e Colonscopie
(diagnostiche ed operative, routinarie ed in Pronta Disponibilità)
-Endoscopia con Videocapsula
- Screening Tumore Colon-Retto
- Visite Gastroenterologiche

We are glad to comunicate that, in our GI department - Gastroenterology and Endoscopy Department U. O. S. D. Dolo Hospital - Steelco S.p.A. AER System (model EW2) installed in 2009 are successfully used with Olympus endoscopes series 140 – 160 – 180 – 190.

Sincerely

Renato Marin
Head Endoscopy Unit.

Regione Veneto-AZIENDA U.L.S.S. N. 13
U.O.S. DIPARTIMENTALE di GASTROENTEROLOGIA
ed ENDOSCOPIA DIGESTIVA
Resp.: Dott. RENATO MARIN
C.F. MRN RNT 52R25 F241H
VE 4808