

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 factories of:

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

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (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 disinfectant and sterilizer for endoscopes

Hydrogen peroxide sterilizer

Hydrogen peroxide sterilizing agent

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.

Reference to IMQ files Nos:

DM13A0183602-01; DM13A0183633-01; DM13A0183664-01; DM15A0428468-01;
DM15A0452415-01; DM16E0607580-01; DM16A0650306-01; DM16-0001448;
DM16-0001754; 10AO00210; DM16-0002039-01; DM16-0006753-01.

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: 2017-05-25
Substitution Date: 2016-12-20
Expiring Date: 2021-02-22

IMQ



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This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

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MOD. 1475A / 2

Annex

Flusher disinfectors / Bedpan washers

Series: BP Type ref. See document LIST OF PRODUCTS CONCERNING TRADE MARK LINE STEELCO Rev. 21, valid only if provided with IMQ stamp.
Trade mark STEELCO

Washer disinfectors

Series: DS ; WD ; LC ; TW Type ref. See document LIST OF PRODUCTS CONCERNING TRADE MARK LINE STEELCO Rev. 21, valid only if provided with IMQ stamp.
Trade mark STEELCO

Endoscope washers

Series: EW 2 Type ref. See document LIST OF PRODUCTS CONCERNING TRADE MARK LINE STEELCO Rev. 21, valid only if provided with IMQ stamp.
Trade mark STEELCO

Decontamination clenears

Series: US ; DC Type ref. See document LIST OF PRODUCTS CONCERNING TRADE MARK LINE STEELCO Rev. 21, valid only if provided with IMQ stamp.
Trade mark STEELCO

Chemical washer disinfectant and sterilizer for endoscopes

Series: EW 1 Type ref. See document LIST OF PRODUCTS CONCERNING TRADE MARK LINE STEELCO Rev. 21, valid only if provided with IMQ stamp.

Hydrogen peroxide sterilizer

Series: PL Type ref. See document LIST OF PRODUCTS CONCERNING TRADE MARK LINE STEELCO Rev. 21, valid only if provided with IMQ stamp.

Hydrogen peroxide sterilizing agent

Series: SteelcoPro PL Type ref. See document LIST OF PRODUCTS CONCERNING TRADE MARK LINE STEELCO Rev. 21, valid only if provided with IMQ stamp.

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PRODUCT CERTIFICATION - 909/MDD
LIST OF PRODUCTS CONCERNING
TRADE MARK LINE

Revision: **21**
 Date: **2017/05/08**
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Flusher Disinfectors / Bedpan washers for medical purpose BP line includes the following changes and names:

	FEEDING	POWER	DOORS		BODY		SET UP
			NUMBER	MOVEMENT	WIDTH	HEIGHT	
BP LINE	<i>Single-phase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Three-phase</i> 200-230V / 50-60Hz 380-480V / 50-60Hz	From 750W to 6900W	1 or 2	MANUAL / SEMI-AUTOMATIC / AUTOMATIC	STANDARD / REDUCED / INCREASED	STANDARD / HIGH	STANDARD / E

Trade names: **BP 100 M, BP 100 A, BP 100 H, BP 100 HA, 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** Technical file: **DT-FT-01_M**

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

	FEEDING	POWER	DOORS		BODY	OPTIONALS
			NUMBER	MOVEMENT		
DS LINES	<i>Single-phase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Three-phase</i> 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: **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** Technical file: **DT-FT-04_M**
DS 500, DS 500 D, DS 500 DRS, DS 500 DRSD, DS 500 DRS4, DS 500 LED, DS 500 LEDD, Technical file: **DT-FT-03_M**
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
DS 650, DS 700, DS 750, DS 750 1S, DS 750 2S, DS 750 3S, DS 800, DS 800 1S, DS 800 2S, Technical file: **DT-FT-06_M**
DS 800 3S
DS 900, DS 900 1S, DS 900 2S, DS 900 3S, DS 1000, DS 1000 1S, DS 1000 2S, DS 1000 3S Technical file: **DT-FT-05_M**

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

	FEEDING	POWER
WD LINES	<i>Single-phase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Three-phase</i> 200-230V / 50-60Hz 380-480V / 50-60Hz	From 13500W to 25000W

Trade names: **WD 1110** Technical file: **DT-FT-06_M**
WD 1115 Technical file: **DT-FT-05_M**

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

	FEEDING	POWER	STATIONS
			NUMBER
TW LINE	<i>Three-phase</i> 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**



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

	FEEDING	POWER	DOORS		LONGITUDINAL DIMENSIONS
			NUMBER	MOVEMENT	
LC LINE	<i>Three-phase</i> 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.
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-12_M
DT-FT-08_M

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

	FEEDING	POWER	DOORS
			NUMBER
US LINE	<i>Single-phase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Three-phase</i> 200-230V /50-60Hz 380-480V / 50-60Hz	Up to 6350W	1 or 2

Trade names:

US 80.
US 100, US 200/1, US 200/2, US 200/3, US 200/4.
US 300.
US 900, US 1000.

Technical file:

DT-FT-20_M
DT-FT-13_M
DT-FT-21_M
DT-FT-07_M

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

	FEEDING	POWER	DOORS
			NUMBER
DC LINE	<i>Single-phase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Three-phase</i> 200-230V /50-60Hz 380-480V / 50-60Hz	Up to 10000W	1 or 2

Trade names:

DC 100, DC 200/1, DC 200/2.
DC 1000/1, DC 1000/2.

Technical file:

DT-FT-17_M
DT-FT-19_M

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

	FEEDING	POWER	DOORS
			NUMBER
EW 2 LINE	<i>Three-phase</i> 200-230V /50-60Hz 380-480V / 50-60Hz	Up to 9100W	1 or 2

Trade names:

EW 2/1, EW 2/2, EW 2/1 2S, EW 2/2 2S, EW 2/1 3S, EW 2/2 3S.

Technical file:

DT-FT-10_M

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Chemical washer disinfectant and sterilizer for endoscopes EW 1 line includes the following changes and names:

	FEEDING	POWER	DOORS
			NUMBER
EW 1 LINE	<i>Single-phase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Three-phase</i> 200-230V / 50-60Hz 380-480V / 50-60Hz	Up to 4500W	1 or 2

Trade names: EW 1	Technical file: DT-FT-18_M
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Hydrogen peroxide sterilizer PL line includes the following changes and names:

	FEEDING	POWER	DOORS
			NUMBER
PL LINE	<i>Three-phase</i> 200-230V / 50-60Hz 380-480V / 50-60Hz	Up to 5000 W	1 or 2

Trade names: PL 70/1, PL 70/2, PL 130/1, PL 130/2	Technical file: DT-FT-27_M
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Hydrogen peroxide sterilizing agent SteelcoPro PL line includes the following changes and names:

	CONCENTRATION
SteelcoPro PL LINE	58% of H ₂ O ₂

Trade names: SteelcoPro PL	Technical file: DT-FT-17_C
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All product specified are sold on the market and identified by technical files
This document is approved by IMQ S.p.A. and immediately effect on the market
This is a translation of the Italian text, which prevails in case of doubts.



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