

# EC CERTIFICATE

Certificate No 1000/MDD

## Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, section 3 of Legislative Decree of 1997-02-24, No 46, national transposition of the Directive 93/42/EEC, we hereby certify that:

### INTERNATIONAL STEEL CO. SPA

manages in the factories of:

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

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

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

#### Bedpan washer disinfecter

Series: REVO Type ref. See document LIST OF PRODUCTS CONCERNING TUTTNAUER  
TRADE MARK LINE, valid only if provided by IMQ stamp.  
Trade mark TUTTNAUER

#### Washer disinfecter

Series: LAVA Type ref. See document LIST OF PRODUCTS CONCERNING TUTTNAUER  
TRADE MARK LINE, valid only if provided by IMQ stamp.  
Trade mark TUTTNAUER

Series: TIVA Type ref. See document LIST OF PRODUCTS CONCERNING TUTTNAUER TRADE  
MARK LINE, valid only if provided by IMQ stamp.  
Trade mark TUTTNAUER

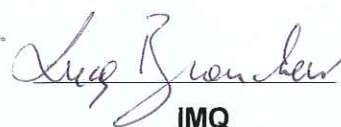
with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

Reference to IMQ files Nos 10AG00225.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC.

Notified Body notified to European Commission under number: 0051.

Date: 2007-02-09  
Updated: 2007-06-04  
Substitution Date: 2007-04-12

  
IMQ

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".  
In any case, it does not remain valid after 2012-02-08 (article 11, clause 11 of the Directive).

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

# PRODUCT CERTIFICATION

## LIST OF PRODUCTS CONCERNING

**TUTTNAUER TRADE MARK LINE**

Revision: **00**  
Date: **2007/01/23**  
Page: **1 di 1**

**Bedpan washers for medical purpose REVO line including following changes and names:**

	FEEDING	POWER	DOORS		BODY		SET UP
			NUMBER	MOVEMENT	WIDTH	HEIGHT	
<b>REVO LINE</b>	<i>Singlephase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Threephase</i> 200-220V / 50-60Hz 380-415V / 50-60Hz	From 750W to 5400W	1 or 2	MANUAL / SEMI-AUTOMATIC / AUTOMATIC	STANDARD / REDUCED / INCREASED	STANDARD / HIGH	STANDARD / E

Trade name:  
**REVO 100 M, REVO 100 A, REVO 100 H, REVO 100 HE, REVO 100 HSE,  
REVO 100 HAE, REVO 100 HSER.**

Technical file:  
**DT-FT-01**

**Washers disinfecter for medical purpose LAVA line including following changes and names:**

	FEEDING	POWER	DOORS		BODY	OPTIONALS	SET UP
			NUMBER	MOVEMENT			
<b>LAVA LINE</b>	<i>Singlephase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Threephase</i> 200-230V / 50-60Hz 380-415V / 50-60Hz	From 2750W to 2950W	1	MANUAL	STANDARD / DRS	WITH DRYING / WITH WATER SOFTNER	STANDARD

Trade name:  
**LAVA 50, LAVA 50 D, LAVA 50 DRS, LAVA 50 DRSD.**

Technical file:  
**DT-FT-04**

**Washers disinfecter for medical purpose TIVA line including following changes and names:**

	FEEDING	POWER	DOORS		BODY	OPTIONALS	SET UP
			NUMBER	MOVEMENT			
<b>TIVA LINE</b>	<i>Singlephase</i> 110V / 60Hz 220-240V / 50-60Hz <i>Threephase</i> 200-230V / 50-60Hz 380-415V / 50-60Hz	From 3050W to 20000W	1 or 2	MANUAL / AUTOMATIC	STANDARD / HIGH	WITH DRYING / 3 or 4 DOSING PUMPS / WITH WATER SOFTNER	STANDARD / LABORATORY

Trade name:  
**TIVA 100, TIVA 100 S, TIVA 100 SD,  
TIVA 500, TIVA 500 D, TIVA 500 DRS, TIVA 500 DRSD, TIVA 500 DRS4, TIVA 500 L,  
TIVA 500 LD, TIVA 600/1, TIVA 600/2,  
TIVA 650, TIVA 700, TIVA 750, TIVA 800,  
TIVA 900, TIVA 1000.**

Technical file:  
**DT-FT-02  
DT-FT-03  
  
DT-FT-06  
DT-FT-05**

**09 FEB. 2007**



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.*