



DECLARATION OF CONFORMITY



Manufacturer **W&H Sterilization S.r.l.**

Address Via Bolgara, 2
I-24060 Brusaporto (BG)
ITALY

Series

Type **RIL-122**
REF **19942123**
Serial Number **169076**

Technical Specifications

Classification (MDD, Annex IX)/Rules : IIb / 15

We herewith declare under our sole responsibility that the above mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of manufacturer and the notified body.

Technical file: TF 21

The sterilizer, sterilization processes and provided documentation are in full compliance with the following applicable DIRECTIVES and STANDARDS.

Directive

Medical Device Directive: COUNCIL DIRECTIVE of 14 June 1993 concerning medical devices (MDD 93/42/EEC amended by Directive 2007/47/EC – DL 24-02-1997, n°46 modified by DL 25-01-2010 n° 37).

Standards

INTERNATIONAL	EUROPEAN	ITALIAN
	EN 13060 2014	UNI EN 13060 2015
IEC 61010-1 2010	EN 61010-1 2010	CEI EN 61010-1 2010
IEC 61010-2-040 2015	EN 61010-2-040 2015	CEI EN 61010-2-040 2016
IEC 61326-1 2012	EN 61326-1 2013	CEI EN 61326-1 2013

Notified Body:

IMQ S.p.A.

Via Quintiliano, 43 – 20138 Milano, Italy

Conformity Assessment Route:

Annex II excluding section 4

Date CE mark was affixed:

Certificate n° 780/MDD of 2021/04/07

ISSUE DATE	APPROVED BY
24 May 2022	 Marino Luigi Magno General Management
W&H Sterilization S.r.l. - Via Bolgara, 2 - 24060 Brusaporto (BG) Italy	



DECLARATION OF CONFORMITY



Manufacturer **W&H Sterilization S.r.l.**

Address Via Bolgara, 2
I-24060 Brusaporto (BG)
ITALY

Product **Sterilization chamber 22 I**
Model Code **S521518X**
Serial Number **123-124344**
Technical Specification

Classification/Category (PED, Annex II, Table 5): II

Design code calculations: SEC VIII Div.1

We herewith declare under our sole responsibility that the above mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of manufacturer and the notified body.

Technical file: TF 10

The sterilization chamber and provided documentation are in full compliance with the following applicable DIRECTIVE and STANDARDS.

Directive

DIRECTIVE 2014/68/EU of 15 May 2014 relating to the making available on the market of pressure equipment (PED 2014/68/EU – DL 15-02-2016, n°26).

Standards:

INTERNATIONAL / EUROPEAN
IEC 61010-1:2010
IEC 61010-2-040: 2015
EN 13060:2014
EN ISO 15609-1:2004
EN ISO 15614-1:2004/A2:2012
EN ISO 9606-1:2013
EN ISO 3834-3:2005

Notified Body: CSI S.p.A. – IMQ Group
V.le Lombardia, 20 – 20021 Bollate, Milan, Italy

Conformity Assessment Route: D1

Date CE mark was affixed: Certificate n° PED/0497/2202/12 of 2021/02/10

ISSUE DATE	APPROVED BY
24 May 2022	  W&H STERILIZATION S.R.L. Via Bolgara, 2 - 24060 Brusaporto (BG) Italy Marino Luigi Magno General Management
W&H Sterilization S.r.l. - Via Bolgara, 2 - 24060 Brusaporto (BG) Italy	



TYPE	REF	SERIAL NUMBER	VOLTAGE\FREQUENCY	POWER SUPPLY
RIL-122	19942123	169076	200-240 V 50/60 Hz	-

The autoclave above mentioned, before shipment, was carried out to following test with the following results:

DESCRIPTION	REFERENCE STANDARDS	TEST SPECIFICATIONS	RESULT	AVAILABLE ON REQUEST
Visual and dimensional test			PASS	YES
Resistance of the equipotential protection circuit	IEC 61010-1:2010	IO-110212	PASS	YES
Insulation resistance			PASS	YES
Dielectric strength			PASS	YES
Leakage current			PASS	YES
Supply current			PASS	YES
Air leakage			EN 13060:2014	PASS
Dynamic sterilizer chamber pressure	PASS			YES
Empty chamber	PASS			YES
Hollow load A	PASS			YES
Full solid load	PASS			YES
Dryness, full solid load	PASS			YES
Hydraulic test – steam generator			PT-S5216080	PASS
Hydraulic test - chamber	2014/68/UE Pressure Equipment Directive (PED)	PT-S5215170	PASS	YES

ISSUE DATE	APPROVED BY
24 May 2022	 W&H Sterilization S.r.l. Via Bolgara, 2 - 24060 Brusaporto (BG) Italy Partita IVA 02855130161 Marco Parolini General Management
W&H Sterilization S.r.l. - Via Bolgara, 2 - 24060 Brusaporto (BG) Italy	



PRODUCT	TYPE	REF	SN
SMALL STEAM STERILIZER	RIL-122	19942123	169076

ELECTRICAL SAFETY TEST

Executed by Silvani on 23 May 2022 at 13:26		Test Result: PASS			
Used Test Equipment: S095	Serial Number: 5240	Next Calibration Date: 02 Dec 2022			
Test Details:					
DESCRIPTION	SET PARAMETERS				TEST RESULT
	V	I/P	t(s)	R/(%)	
Ground test	12 V	25 A	3	100 mΩ	R=51 mΩ
Insulation test	500 V		3	2 MΩ	R>2 MΩ
Leakage test	264 V	4 mA	4		I=1.93mA
Dielectric strength test	1400 V	35 mA	2		OK !

WORKS TEST EQUIPMENT

Inverter Configuration:	
I029	230 V - 50 Hz

Test equipment S216			
Serial Number:		106-0000060	
Next Calibration Date:		28 Sep 2022	
Sensors and probes:			
Pressure sensors		Temperature probes	
PST2	SN11083VEI	TS1	Thermocouple type J SN0001
PST3	SN 503165	TS2	Thermocouple type J SN0002
		TS3	Thermocouple type J SN0003



PRODUCT	TYPE	REF	S/N
SMALL STEAM STERILIZER	RIL-122	19942123	169076

1st Work Test

Test Result: **PASS**

Vacuum test, Id 183, ver 0.1, type/load AirLeakage/None

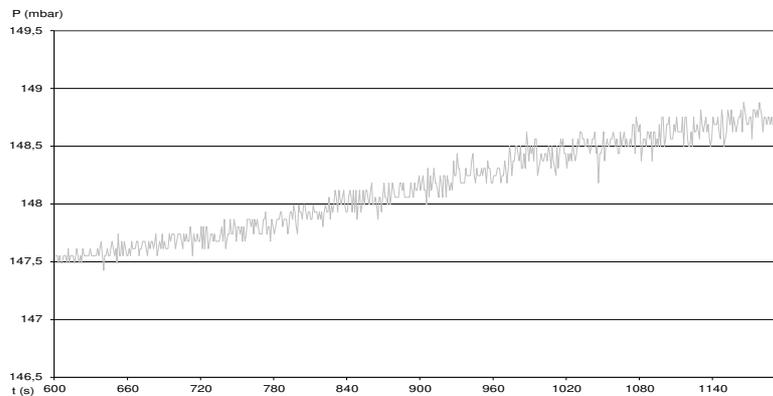
Launched by Stefano Matessich on 23 May 2022 at 13:36 and released by Stefano Matessich

Used Test Equipment: S216 Ambient temperature: 27,6 °C Atmospheric pressure: 980,5 mbar

Test Details:

Description	Acceptance criteria		Measured	Result
Pressure achieved in P1	≥ 103 mbar/s	≤ 183 mbar/s	147 mbar/s	PASS
Time elapsed between P1 and P2	≥ 299 s	≤ 301 s	300 s	PASS
Leakage between P1 and P2	≤ 80 mbar	-	1 mbar	PASS
Time elapsed between P2 and P3	≥ 599 s	≤ 601 s	600 s	PASS
Leakage between P2 and P3	≤ 13 mbar	-	1 mbar	PASS

Pressure Chamber Chart from t2 to t3



2nd Work Test

Test Result: **PASS**

Empty, Id 184, ver 0.0, type/load EmptyChamber/None

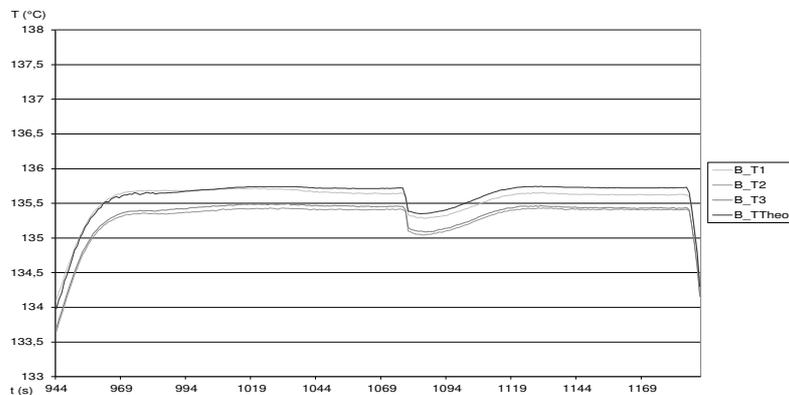
Launched by Stefano Matessich on 24 May 2022 at 07:09 and released by Stefano Matessich

Used Test Equipment: S216 Ambient temperature: 26,6 °C Atmospheric pressure: 979,0 mbar

Test Details:

Description	Acceptance criteria		Measured	Result
Equilibration Time	≤ 15 s	-	3 s	PASS
Holding Time	≥ 239 s	-	245 s	PASS
All Temperatures including Ttheo during Holding Time	≥ 134,0 °C	≤ 137,0 °C	in the range	PASS
All ΔTemperatures during Holding time (including Ttheo)	≤ 2,0 °C	-	in the range	PASS

Plateau Chart





PRODUCT	TYPE	REF	S/N
SMALL STEAM STERILIZER	RIL-122	19942123	169076

3rd Work Test Test Result: **PASS**

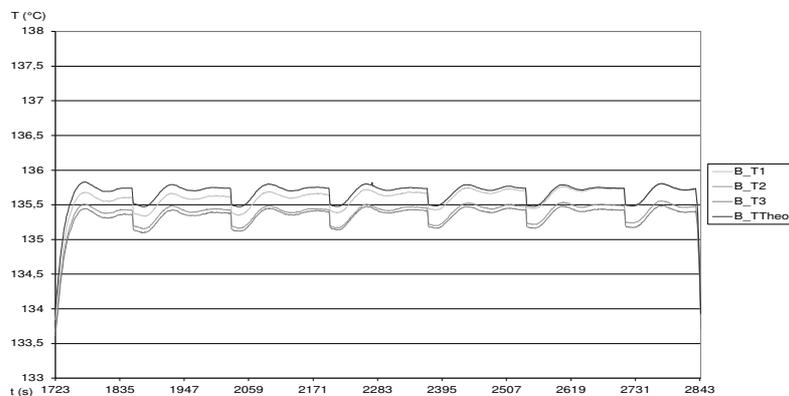
Full Solid, Id 186, ver 0.0, type/load SolidLoadDoubleWrapped/5,5kg±0,7kg

Launched by Stefano Matessich on 24 May 2022 at 08:24 and released by Stefano Matessich
 Used Test Equipment: S216 Ambient temperature: 26,7 °C Atmospheric pressure: 980,6 mbar

Test Details:

Description	Acceptance criteria		Measured	Result
Equilibration Time	≤ 30 s	-	5 s	PASS
Holding Time	≥ 1080 s	-	1116 s	PASS
All Temperatures including Ttheo during Holding Time	≥ 134,0 °C	≤ 137,0 °C	in the range	PASS
All ΔTemperatures during Holding time (including Ttheo)	≤ 2,0 °C	-	in the range	PASS
loadΔW%	no visible moisture	< 0,2%	0,05%	PASS

Plateau Chart



4th Work Test Test Result: **PASS**

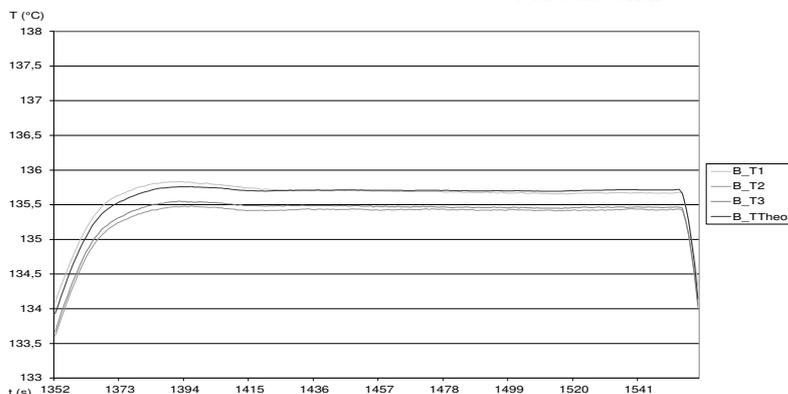
Hollow A, Id 189, ver 0.0, type/load HollowLoadA/Pcd

Launched by Stefano Matessich on 24 May 2022 at 06:37 and released by Stefano Matessich
 Used Test Equipment: S216 Ambient temperature: 25,5 °C Atmospheric pressure: 979,7 mbar

Test Details:

Description	Acceptance criteria		Measured	Result
Equilibration Time	≤ 15 s	-	4 s	PASS
Plateau Time	≤ 211 s	-	209 s	PASS
All Temperatures including Ttheo during Holding Time	≥ 134,0 °C	≤ 137,0 °C	in the range	PASS
All ΔTemperatures during Holding time (including Ttheo)	≤ 2,0 °C	-	in the range	PASS

Plateau Chart



EN867-S 132-137°C **BROWNE**

TEST PASSED

+STEAM=DARK ✓

TEST PASSED



PRODUCT	TYPE	REF	S/N
SMALL STEAM STERILIZER	RIL-122	19942123	169076

5th Work Test Test Result: **PASS**

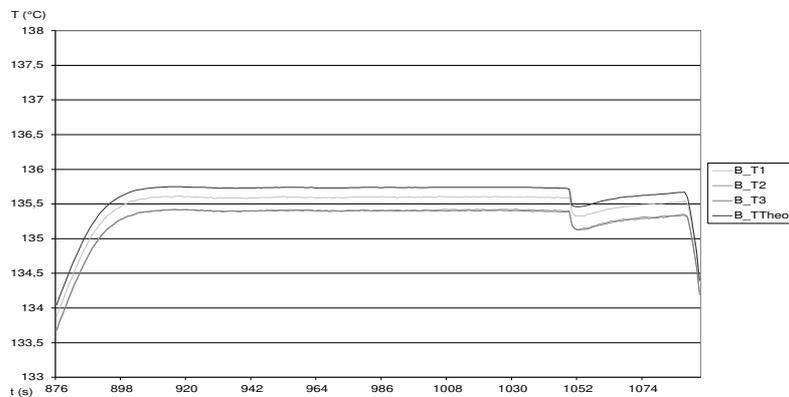
Full Solid Fast, Id 192, ver 0.1, type/load SolidLoad/2kg±0,3kg

Launched by Stefano Matessich on 24 May 2022 at 07:41 and released by Stefano Matessich
 Used Test Equipment: S216 Ambient temperature: 26,3 °C Atmospheric pressure: 980,6 mbar

Test Details:

Description	Acceptance criteria		Measured	Result
Equilibration Time	≤ 30 s	-	3 s	PASS
Holding Time	≥ 209 s	-	215 s	PASS
All Temperatures including Ttheo during Holding Time	≥ 134,0 °C	≤ 137,0 °C	in the range	PASS
All ΔTemperatures during Holding time (including Ttheo)	≤ 2,0 °C	-	in the range	PASS

Plateau Chart



6th Work Test Test Result: **PASS**

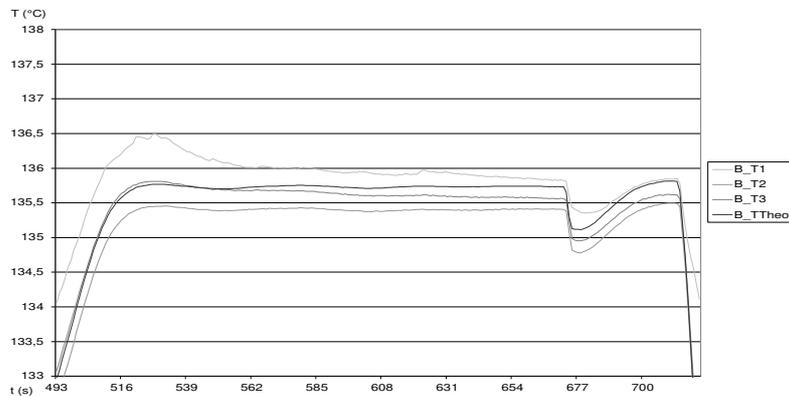
Empty Fast, Id 191, ver 0.1, type/load HollowLoadA/None

Launched by Stefano Matessich on 24 May 2022 at 08:05 and released by Stefano Matessich
 Used Test Equipment: S216 Ambient temperature: 26,8 °C Atmospheric pressure: 980,6 mbar

Test Details:

Description	Acceptance criteria		Measured	Result
Equilibration Time	≤ 15 s	-	10 s	PASS
Holding Time	≥ 209 s	-	213 s	PASS
All Temperatures including Ttheo during Holding Time	≥ 134,0 °C	≤ 137,0 °C	in the range	PASS
All ΔTemperatures during Holding time (including Ttheo)	≤ 2,0 °C	-	in the range	PASS

Plateau Chart





TYPE	REF NUMBER	SN	VOLTAGE/FREQUENCY	POWER SUPPLY
RIL-122	19942123	169076	200-240 V 50/60 Hz	-

TRACEABILITY

DESCRIPTION	SERIAL NUMBER
Pressure safety Valve 5 bar	156-022039189
Pressure safety valve 2.6 bar	088-022155132
Door locking system	090-44136
Pressure Transducer	100-110HI3B2
Sterilization chamber 22 l	123-124344
Electronic Control Board	139-015720
Steam Generator	163-003230
MMI board	164-007825
Vacuum pump	198-0001985
DESCRIPTION	SOFTWARE VERSION
Config. J1000160	Conf_RIL-1_STD
Firmware J1000160	005.018

ISSUE DATE	FILLED BY	APPROVED BY
24 May 2022	Quality Control	 Marco Parolini General Management
W&H Sterilization S.r.l. - Via Bolgara, 2 - 24060 Brusaporto (BG) Italy		



TYPE	REF	SERIAL NUMBER	VOLTAGE\FREQUENCY	POWER SUPPLY
RIL-122	19942123	169076	200-240 V 50/60 Hz	-

The autoclave above mentioned, before shipment, was carried out to the following test with the following results:

DESCRIPTION	RESULT	AVAILABLE ON REQUEST
Air Leakage	PASS	YES
Empty 134° C	PASS	YES
Empty 121° C	PASS	YES

According to EN 13060 (small steam sterilizers European Norm), your sterilizer must be "WORKS TESTED" by the manufacturer W&H STERILIZATION. The complete tests, work and final tests, which are documented, replace the installation test and validation test as per EN 13060.

Further validation might be required by national guidelines.

ISSUE DATE	APPROVED BY
24 May 2022	 W&H Sterilization S.r.l. Via Bolgara, 2 - 24060 Brusaporto (BG) Italy Partita IVA 02889130181 Marco Parolini General Management
W&H Sterilization S.r.l. - Via Bolgara, 2 - 24060 Brusaporto (BG) Italy	