

Declaration of Conformity for Steam Sterilisers (MD)

Issued in accordance with relating to Medical Device Regulation (EU) 2017/745

Manufacturer: Name: Tuttnauer Ltd.
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Notified Body: Name: DEKRA Certification B.V
Address: Meander 1051
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Notified Body Identification# 0344

Product: Steam Sterilizers
See Annex 1 for more details
Basic UDI-DI TTA: 729011064TTAJC
Basic UDI-DI HOR: 729011064HORH3

Classification: Class IIb

Applied harmonized standards:

- ISO 9001:2015, Quality Management Systems
- ISO 13485:2016, Medical devices - Quality Management Systems

Tuttnauer Ltd. states that this declaration is issued under the sole responsibility of the organization and covers all the range of Tuttnauer Steam Sterilizers (Table-Top autoclaves and Horizontal autoclaves).

Tuttnauer Ltd. ensure and declare that the distributed CE marked products, as mentioned in **Annex 1** of this document, and falling within the above-mentioned classification are in conformity with the Regulation (EU) 2017/745 and, where applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex IX of the MDR. The conformity of the full quality assurance system set out in Annex IX, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V., certificate no. 3903015CE01.

Additional information:

This document is supported by the Quality Management System certification based on the harmonized standards:

ISO 13485:2016, Medical devices - Quality Management Systems, certification no. 2122621 first issued by DEKRA Certification B.V

First Issue: March 9, 2023

Valid until: March, 1, 2028

Sign for and on behalf of: Tuttnauer Ltd. Beit Shemesh, Israel, 9, March, 2023
By: Keren Ziv, VP QA & RA, Tuttnauer Ltd.



Signature: _____

Annex 1 – CE marked product list of Steam Sterilizer

The following product list specifies the CE marked products that Tuttnauer intends to distribute in conformity with the provisions of the Medical Device Regulation (MDR) 2017/745:

Model name	Catalogue number	Chamber Dimensions (W x H x D) [mm]	UDI-DI	UM
Table Top (PG controller)				
TTA2340-PG15EA	TTA2340-PGEA	Ø 230 x 470	07290110642037	MAN205-0181002EN
TTA2340-PG15EP	TTA2340-PGE	Ø 230 x 470	07290110642044	
TTA2340-PG23EKA	TTA2340-PGEKA	Ø 230 x 470	07290110642051	
TTA2540-PG15E	TTA2540-PGE	Ø 250 x 470	07290110642068	
TTA2540-PG15EA	TTA2540-PGEA	Ø 250 x 470	07290110642075	
TTA2540-PG23EKA	TTA2540-PGEKA	Ø 250 x 470	07290110642082	
TTA3140-PG23E	TTA3140-PGE	Ø 310 x 47	07290110642099	
TTA3850-PG23E	TTA3850-PGE	Ø 380 x 500	07290110642105	
TTA3850-PG23EA	TTA3850-PGEA	Ø 380 x 500	07290110642013	
TTA3870-PG23E	TTA3870-PGE	Ø 380 x 690	07290110642112	
TTA3870-PG23EA	TTA3870-PGEA	Ø 380 x 690	07290110642129	
Table Top (D-Type)				
2340EKA – D	2340EKA – D	Ø 230 x 470	07290110642150	MAN205-0494005EN
2840E – D	2840E – D	Ø 280 x 504	07290110642167	MAN205-0494006EN
2840EA – D	2840EA – D	Ø 280 x 504	07290110642174	MAN205-0494005EN
2840EKA – D	2840EKA – D	Ø 280 x 504	07290110642198	MAN205-0494005EN
3850EA – D	3850EA – D	Ø 380 x 500	07290110642204	MAN205-0494005EN
3870EA – D	3870EA – D	Ø 380 x 690	07290110642211	MAN205-0494005EN
Elara 9 – D	Elara 9 – D	Ø 230 x 470	07290110642228	MAN205-0497003EN
Elara 11 – D	Elara 11 – D	Ø 280 x 470	07290110640002	MAN205-0497003EN
3870 HSG – D	3870HSG-D	Ø 380 x 760	07290110642235	MAN205-0446010EN
Table Top : T-Edge Family				
T-Edge10	T-Edge10-W	Ø 250 x 460	07290110640446	MAN205-0502025EN
T-Edge11	T-Edge11-W	Ø 280 x 460	07290110640729	MAN205-0502029EN
T-TOP 10	T-TOP 10	Ø 249 x 450	07290110642242	MAN205-0502037EN
Horizontal				
4472	4472-1V	408 x 408 x 730	07290110640200	MAN205-0801008ENO
	4472-1R		07290110640194	
	4472-2R		07290110640415	
	4472-2V		07290110640668	
4480	4480-1V	408 x 408 x 845	07290110641009	
	4480-2R		07290110641016	
	4480-1R		07290110641023	
	4480-2V		07290110641030	
4496	4496-2R	408 x 408 x 970	07290110641047	
	4496-1V		07290110641054	
	4496-1R		07290110641061	
	4496-2V		07290110641078	

Model name	Catalogue number	Chamber Dimensions (W x H x D) [mm]	UDI-DI	UM
5596	5596-2R	508 x 508 x 970	07290110640231	MAN205-0801006ENO
	5596-2V		07290110640248	
	5596-1R		07290110640217	
	5596-1V		07290110640224	
55120	55120-1R	508 x 508 x 1210	07290110641085	MAN205-0801006ENO
	55120-2R		07290110641092	
	55120-1V		07290110641108	
	55120-2V		07290110641115	
6690	6690-2A	610 x 610 x 915	07290110640767	MAN205-0801010ENO
	6690-2R		07290110641122	
	6690-2V		07290110641139	
	6690-1V		07290110641146	
	6690-1A		07290110640286	
66120	66120-2V	610 x 610 x 1215	07290110641153	MAN205-0801010ENO
	66120-2R		07290110641160	
	66120-1V		07290110640255	
	66120-1A		07290110641177	
	66120-2A		07290110641184	
6671130	6671130-2A	660 x 710 x 1295	07290110641191	MAN205-0801012ENO
	6671130-1A		07290110641207	
	6671130-1V		07290110641214	
	6671130-2V		07290110641221	
6671162	6671162-1A	660 x 710 x 1620	07290110641238	MAN205-0801012ENO
	6671162-2V		07290110641245	
	6671162-1V		07290110641252	
	6671162-2A		07290110641269	
667166	667166-2V	660 x 710 x 660	07290110641276	MAN205-0801012ENO
	667166-1V		07290110641283	
667199	667199-2V	660 x 710 x 990	07290110641290	MAN205-0801012ENO
	667199-1V		07290110641306	
6671197	6671197-2V	660 x 710 x 1970	07290110641313	MAN205-0801012ENO
	6671197-1V		07290110641320	
6990	6990-2R	610 x 910 x 915	07290110641337	MAN205-0801014ENO
	6990-2A		07290110641344	
	6990-1A		07290110640392	
	6990-2H		07290110641351	
	6990-1H		07290110641368	
69120	69120-1R	610 x 910 x 1215	07290110640347	MAN205-0801014ENO
	69120-1A		07290110640330	
	69120-1H		07290110641375	
	69120-2H		07290110641382	
	69120-2A		07290110640354	
69150	69150-2A	610 x 910 x 1515	07290110640422	MAN205-0801014ENO
	69150-1A		07290110640378	
	69150-1H		07290110641399	
	69150-2R		07290110641405	
	69150-2H		07290110641412	
69180	69180-2A	610 x 910 x 1815	07290110641429	MAN205-0801014ENO
	69180-1H		07290110641436	
	69180-2H		07290110641443	
	69180-1A		07290110640385	
66158195 (266276 – 2H)	266276-2H	---	07290110641450	MAN205-0801016ENO
T- Max 2	T-MAX 2-1V	360 x 710 x 680	07290110641467	MAN205-0801018ENO
	T-MAX 2-2V		07290110641474	

Model name	Catalogue number	Chamber Dimensions (W x H x D) [mm]	UDI-DI	UM
T- Max 4	T-MAX 4-1V T-MAX 4-2V	660 x 660 x 705	07290110641481 07290110641498	MAN205-0801020ENO
T- Max 6	T-MAX 6-1V T-MAX 6-2V	660 x 660 x 990	07290110641504 07290110641511	
T- Max 8	T-MAX 8-1V T-MAX 8-2V	660 x 660 x 1295	07290110641528 07290110641535	
T- Max 9	T-MAX 9-1H T-MAX 9-2H	660 x 1220 x 990	07290110641542 07290110641559	
T- Max 10	T-MAX 10-1V T-MAX 10-2V T-MAX 10L-2V	660 x 660 x 1620	07290110641566 07290110641573 07290110641740	
T- Max 12	T-MAX 12-1H T-MAX 12-2H T-MAX 12-1V T-MAX 12-2V T-MAX 12L-1H T-MAX 12L-2H T-MAX 12L-1V T-MAX 12L-2V	660 x 1220 x 1295	07290110641580 07290110641597 07290110641603 07290110641610 07290110641702 07290110641719 07290110641726 07290110641733	MAN205-0801022ENO
T- Max 15	T-MAX 15-1H T-MAX 15-2H	660 x 1220 x 1620	07290110641627 07290110641634	
5075 HSG	5075HSG-D 5075HSG-MD	Ø 500 x 750	07290110641641 07290110641658	
5075GS	5075GS-1A 5075GS-2A	Ø 500 x 750	07290110641665 07290110641672	
50125GS	50125GS-1A 50125GS-2A	Ø 500 x 1250	07290110641689 07290110641696	

The following table is the legend to the affix letters that may be added to the device label including combination of these letters :

Letters	Description	Letters	Description
1R	One manual door	EP	Internal steam generator
2R	Two manual doors	SP	External steam generator
1V	One vertical door	EL	Steam generator left side
2V	Two vertical door	ER	Steam generator right side
1H	One horizontal door	D	D-line
2H	Two horizontal door	MD	Manual door
1A	One automatic door	G	Generator
2A	Two automatic door	WS/W	External water system
C	Cabinet (external panels)	P	Printer
N	Neutral (electricity)		
PG	Pre-DG		

Revision History

Version #	Change Description	Editor	Date
1	New document	Keren Ziv	09-03-2023