

**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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SRN: IL-MF-000028057

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**Notified Body:** Name: DEKRA Certification B.V  
Address: Meander 1051  
6825 MJ Arnhem  
The Netherlands  
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
<b>Table Top (PG controller)</b>				
TTA2340-PG15EA	TTA2340-PGEA	∅ 230 x 470	07290110642037	MAN205-0181002EN
TTA2340-PG15EP	TTA2340-PGE	∅ 230 x 470	07290110642044	
TTA2340-PG23EKA	TTA2340-PGEKA	∅ 230 x 470	07290110642051	
TTA2540-PG15E	TTA2540-PGE	∅ 250 x 470	07290110642068	
TTA2540-PG15EA	TTA2540-PGEA	∅ 250 x 470	07290110642075	
TTA2540-PG23EKA	TTA2540-PGEKA	∅ 250 x 470	07290110642082	
TTA3140-PG23E	TTA3140-PGE	∅ 310 x 47	07290110642099	
TTA3850-PG23E	TTA3850-PGE	∅ 380 x 500	07290110642105	
TTA3850-PG23EA	TTA3850-PGEA	∅ 380 x 500	07290110642013	
TTA3870-PG23E	TTA3870-PGE	∅ 380 x 690	07290110642112	
TTA3870-PG23EA	TTA3870-PGEA	∅ 380 x 690	07290110642129	
<b>Table Top (D-Type)</b>				
2340EKA – D	2340EKA – D	∅ 230 x 470	07290110642150	MAN205-0494005EN
2840E – D	2840E – D	∅ 280 x 504	07290110642167	MAN205-0494006EN
2840EA – D	2840EA – D	∅ 280 x 504	07290110642174	MAN205-0494005EN
2840EKA – D	2840EKA – D	∅ 280 x 504	07290110642198	MAN205-0494005EN
3850EA – D	3850EA – D	∅ 380 x 500	07290110642204	MAN205-0494005EN
3870EA – D	3870EA – D	∅ 380 x 690	07290110642211	MAN205-0494005EN
Elara 9 – D	Elara 9 – D	∅ 230 x 470	07290110642228	MAN205-0497003EN
Elara 11 – D	Elara 11 – D	∅ 280 x 470	07290110640002	MAN205-0497003EN
3870 HSG – D	3870HSG-D	∅ 380 x 760	07290110642235	MAN205-0446010EN
<b>Table Top : T-Edge Family</b>				
T-Edge10	T-Edge10-W	∅ 250 x 460	07290110640446	MAN205-0502025EN
T-Edge10	T-Edge10	∅ 250 x 460	07290110640842	MAN205-0502025EN
T-Edge11	T-Edge11-W	∅ 280 x 460	07290110640729	MAN205-0502029EN
T-Edge11	T-Edge11	∅ 280 x 460	07290110640712	MAN205-0502029EN
T-TOP 10	T-TOP 10	∅ 249 x 450	07290110642242	MAN205-0502037EN
<b>Horizontal</b>				
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		
	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		
	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		
	6671162-2V		07290110641245		
	6671162-1V		07290110641252		
	6671162-2A		07290110641269		
667166	667166-2V	660 x 710 x 660	07290110641276		
	667166-1V		07290110641283		
667199	667199-2V	660 x 710 x 990	07290110641290		
	667199-1V		07290110641306		
6671197	6671197-2V	660 x 710 x 1970	07290110641313		
	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		
	69120-1A		07290110640330		
	69120-1H		07290110641375		
	69120-2H		07290110641382		
	69120-2A		07290110640354		
69150	69150-2A	610 x 910 x 1515	07290110640422		
	69150-1A		07290110640378		
	69150-1H		07290110641399		
	69150-2R		07290110641405		
	69150-2H		07290110641412		
69180	69180-2A	610 x 910 x 1815	07290110641429		
	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	660 x 660 x 705	07290110641481	MAN205-0801020ENO	
	T-MAX 4-2V		07290110641498		
T- Max 6	T-MAX 6-1V	660 x 660 x 990	07290110641504		
	T-MAX 6-2V		07290110641511		
T- Max 8	T-MAX 8-1V	660 x 660 x 1295	07290110641528		
	T-MAX 8-2V		07290110641535		
T- Max 9	T-MAX 9-1H	660 x 1220 x 990	07290110641542		MAN205-0801022ENO
	T-MAX 9-2H		07290110641559		
T- Max 10	T-MAX 10-1V	660 x 660 x 1620	07290110641566	MAN205-0801020ENO	
	T-MAX 10-2V		07290110641573		
	T-MAX 10L-2V		07290110641740		
T- Max 12	T-MAX 12-1H	660 x 1220 x 1295	07290110641580	MAN205-0801022ENO	
	T-MAX 12-2H		07290110641597		
	T-MAX 12-1V		07290110641603		
	T-MAX 12-2V		07290110641610		
	T-MAX 12L-1H		07290110641702		
	T-MAX 12L-2H		07290110641719		
	T-MAX 12L-1V		07290110641726		
	T-MAX 12L-2V		07290110641733		
T- Max 15	T-MAX 15-1H	660 x1220 x 1620	07290110641627	MAN205-0446010EN	
	T-MAX 15-2H		07290110641634		
5075 HSG	5075HSG-D	∅ 500 x 750	07290110641641	MAN205-0446010EN	
	5075HSG-MD		07290110641658		
5075GS	5075GS-1A	∅ 500 x 750	07290110641665	MAN205-1000001EN	
	5075GS-2A		07290110641672		
50125GS	50125GS-1A	∅ 500 x 1250	07290110641689		
	50125GS-2A		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
2	Addition of T-Edge 10 and 11 to the T-Edge family W\O "W"	Keren Ziv	22-10-2023