



## Manufacturer's Declaration of Conformity (in accordance with ISO/IEC 17050-1)

Issuer's name:

Tuttnauer Europe B.V.

Issuer's address:

Hoeksteen 11 P.O. Box 7191 4800 GD Breda The Netherlands

Object of the declaration:

Laboratory Autoclaves

Model Codes:

See Addendum: product list

In addition we ensure and declare that the distributed products, as mentioned, meet the relevant provisions.

Document

Title

- Directive 2006/42/EC

Machine Directive

- Directive 2014/35/EU

Low Voltage Directive

- Directive 2014/30/EU

**EMC** Directive

- Directive 2014/68/EU

Pressure Equipment Directive

- EN 61326-1:2013

Electrical equipment for measurement, control and laboratory use

**EMC** requirements

- EN 61010-1:2010

Safety requirements for electrical equipment for measurement,

control and laboratory use

- EN 61010-2-040:2015

Safety requirements for sterilizers and washer-disinfectors used

to treat medical materials.

All harmonized standards which are applicable to the object, as published in the Official Journal of the European Communities.

## Additional information:

Notified Body:

Dekra Certification BV

Meander 1051 6825 MJ Arnhem The Netherlands

First issue date certificate:

February 14, 2010

Valid until:

February 1, 2024

This documentation is supported by the Quality Management System certification based on the harmonized standard ISO 9001:2015, Quality Management System Certificate with reference numbers: 2129743, issued for the 1st time on February 14, 2010, and delivered by Dekra Certification 9

Signed for and on behalf of:

Breda, The Netherlands, 18 April 2021

Name:

Keren Ziv

Function:

QA&RA Manager, Tuttnauer Europe B.V

Signature:

( Tab





## **ADDENDUM: Product List**

## **Laboratory Series**

Model	Inner Dimensions Diameter x Depth	Volume
	(mm)	Liters
EL-D Series - Fully A	utomatic	
2840EL-D	280 x 400	28
3850EL-D	380 x 500	65
3870EL-D	380 x 690	85
5075EL-D	500 x 750	160
ELC-D Series - Fully	Automatic with Rapid Cooling	
3850ELC-D	380 x 500	65
3870ELC-D	380 x 690	85
5050ELC-D	500 x 500	110
5075ELC-D	500 x 750	160
ELV-D Series - Fully	Automatic, Vertical	
2840ELV-D	280 x 460	31
3850ELV-D	380 x 500	65
3870ELV-D	380 x 690	* 85
5050ELV-D	500 x 500	110
5075ELV-D	500 x 750	160
ELVC-D Series - Ful	lly Automatic, Vertical, with Rapid Cooling	
3850ELVC-D	380 x 500	65
3870ELVC-D	380 x 690	85
5050ELVC-D	500 x 500	110
5075ELVC-D	500 x 750	160

The affix letters: + BH, C, F, G, PV, W, WR, WS may be added to the device label including combination of these letters.

Doc.number: 1100-0015.10 Page 2 of 2