

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 Autoclave T-Lab ECO V85

We ensure and declare that the distributed products, as mentioned below, complies with the essential requirements of the following applicable European Directive(s), and carries the CE marking accordingly:

- IEC 61010-1:2010/AMD1:2016/COR1:2019 \ EN 61010-1:2010+A1:2019 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- EN IEC 61010-2-040:2021 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
- EN 61326-1:2013; 2020 EMC requirements for electrical equipment
- CE marking Pressure Equipment 2014/68/EU PED Pressure Equipment Directive Module H. CE1128 valid till 14.11.2022

- ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- ISO 9001:2015 Quality management systems — Requirements

Signed for and on behalf of: Breda, The Netherlands, 15 September, 2022

Name: K. Ziv

Function: VP QA&RA

Signature: