Number: 3903015CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Tuttnauer Ltd.

Har-Tuv B Industrial Zone,
P.O Box 170
9910101 Beit Shemesh,
Israel
SRN ID.: IL-MF-000028057

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2123763CN

Authorized Representative: Tuttnauer Europe B.V., Hoeksteen 11 4815 PR Breda, The Netherlands

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Principal Certification Manager

First Issued: **09-03-2023** Date: **09-03-2023** Expiry date**: 01-03-2028**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

CLEANING, DISINFECTION AND STERILIZATION INSTRUMENTS-OTHER, (Z12011399, class IIb)	
Group of Devices: • **Table-Top autoclaves** • **Horizontal autoclaves**	*Intended Purpose: The autoclave is designed for sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities (e.g. hospitals, nursing homes extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices) and laboratories.*

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Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	09-03-2023	2123763CN23	First issue

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