CERTIFICATE

Number: 2122621

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Tuttnauer Ltd.

Har - Tuv B Industrial Zone P.O. Box 170 Beit Shemesh 9910101 Israel

including the implementation meets the requirements of the standard:

ISO 13485:2016 EN ISO 13485:2016

Scope:

Design, Development, manufacturing, installation, service and distribution of Steam, and Hydrogen peroxide low temperature Sterilizers for use with medical devices Distribution of Hydrogen Peroxide sterilizing Agent as accessory for use with Hydrogen peroxide low temperature sterilizer

Certificate expiry date: 1 February 2024 / Certificate effective date: 1 July 2021 / Certified since: 12 February 2009

This certificate is valid for the organization(s) and/or locations mentioned on the addendum

DEKRA Certification B.V.

B.T.M. Holtus Managing Director J.A. van Vugt Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



DEKRA THE PRINCE OF PRINCE

ADDENDUM

To certificate: 2122621

The management system of the organization(s) and/or location(s) of:

Tuttnauer Ltd.

Har - Tuv B Industrial Zone P.O. Box 170 Beit Shemesh 9910101 Israel

Certified organization(s) and/or locations:

Different scope

Tuttnauer, Ltd. 30 Hayotzrim St. Nahariya 22311

Manufacturing of Hydrogen peroxide low temperature sterilizer and warehouse storage of components for Tuttnauer

Addendum expiry date: 1 February 2024 Addendum effective date: 1 July 2021