Medalkan
HYGIENE & DISINFECTION

DECLARATION OF CONFORMITY EU
(According to Regulation (EU) 2017/745, Article 19, ANNEX IV)

We hereby, **TECHNIKI EMPORIKI STAVRIDIS LTD - MEDALKAN** manufacturer of Medical Device class I, declare that:

For the medical device included in this EU Declaration of Conformity, the requirements set out in Regulation (EU) 2017/745 are met.

This declaration of conformity is our own responsibility and contains at least the information set out in Annex IV.

A. DETAILS OF THE MANUFACTURER

A'1. Name, registered trademark / registered trademark & SRN (if already issued)

TECHNIKI EMPORIKI STAVRIDIS LTD / MEDALKAN

A'2. Registered office address & contact details

102, MICHALAKOPOULOU STREET, 115-28 ATHENS, GREECE
TEL: +30 210 7484847
EMAIL: contact@medalkan.gr

B. DETAILS OF MEDICAL DEVICE

PRODUCT 1

B.1. BASIC UDI-DI (Annex VI part C): 5214001621CLASS1JN

5 214001 621538
(1L)

5 214001 621545
(5L)

B.2. Product name and brand name: **T-CLEAN A - TUTTNAUER**

- Product reference: 20064 (1L), 20065 (5L)

- Intended use: Alkaline detergent for the reprocessing of surgical instruments and equipment

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PRODUCT 2

B.1. BASIC UDI-DI (Annex VI part C): 5214001621CLASS1JN

(1L)

(5L)

B.2. Product name and brand name: **T-CLEAN E - TUTTNAUER**

- Product reference: 20066 (1L), 20067 (5L)

- Intended use: Tri- Enzymatic cleaner for endoscopes and surgical instruments

PRODUCT 3

B.1. BASIC UDI-DI (Annex VI part C): 5214001621CLASS1JN

(1L)

(5L)

B.2. Product name and brand name: **T-CLEAN E 6 PLUS - TUTTNAUER**

- Product reference: 20068 (1L), 20069 (5L)

- Intended use: Multi enzymatic detergent for surgical instruments and endoscopes

PRODUCT 4

B.1. BASIC UDI-DI (Annex VI part C): 5214001621CLASS1JN

(1L)

(5L)

B.2. Product name and brand name: **T-CLEAN N - TUTTNAUER**

- Product reference: 20070 (1L), 20071 (5L)

- Intended use: Acidic neutralising agent instrument renovator

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PRODUCT 5

B.1. BASIC UDI-DI (Annex VI part C): 5214001621CLASS1JN

(1L)

(5L)

B.2. Product name and brand name**T-CLEAN R - TUTTNAUER**

- Product reference: 20072 (1L), 20073 (5L)

- Προβλεπόμενη χρήση Rinse aid for the automated reprocessing of surgical instruments and equipment

PRODUCTS 1, 2, 3, 4, 5

Classification rule, product risk category according to the classification rules of Annex VIII of Regulation (EU) 745/2017:

- **Class I non-invasive medical devices, rule I**

B.3. Not applicable

B.4. References to any Common Specifications / Standards used and based on which compliance is declared:

ISO 9001:2015, ISO 13485:2016, ΔΥ8δ/1348, EN ISO 14971:2012, MEDDEV 2.7.1 Rev. 4, 2016, EN ISO 10993:2018, EN ISO 15223-1:2016, CIPAC (Collaborative International Pesticides Analytical Council) MT 46-3.

B.5. Additional information as appropriate: NONE

C. I hereby declare that:

C.1. The medical device covered by this declaration meet the specifications contained in the technical portfolio of products, which includes the elements set out in Annexes II and III of Regulation no. (EU) 2017/745, as applicable, and is updated whenever and as required by the Regulation.

C.2. The medical device covered by this declaration comply with the requirements of Regulation no. (EU) 2017/745 and with the requirements of any other EU legislation applicable to the MEDICAL DEVICE of this declaration.

C.3. The EU Declaration of Conformity will be updated on an ongoing basis.

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C.4. The medical device covered by this declaration meet the general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 and are therefore valid, in accordance with their intended use herein. with the classification rules of Annex VIII of Regulation no. (EU) 2017/745.

Athens, November the 22nd. 2022.

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Director

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