

# DECLARATION OF CONFORMITY

№ 2/2018

**Manufacturer:** KENTAMED Ltd.

**Address:** Head office: bl.154, entr.B, ap.25, Housing estate "Trakia", 4023 Plovdiv, Bulgaria  
Production facility: 41 Nestor Abadjiev str., 4023 Plovdiv, Bulgaria  
Phone: (+359 32) 622934, FAX: (+359 32) 622934, E-mail: sales@kentamed.com

**Product:** Electrosurgical unit **KENTAMED hARTT 200/250/300/400**

**We declare that the above-mentioned medical device is in conformity with the Essential Requirements of:**

**Document №**  
Medical Device Directive 93/42/EEC; 2007/47/EC

**Title**  
Medical devices: General

**For achievement of the conformity are performed the requirements of:**

All applicable Harmonized standards.

**Additional information:**

The above-mentioned electrosurgical units **KENTAMED hARTT 200/250/300/400** is classified as **Class IIb** according the rules in Annex IX of MDD 93/42/EEC; 2007/47/EC.

The Declaration of conformity is issued on the base of Annex II of MDD 93/42/EEC "Full Quality Assurance System" and on the base of **Certificate Nr. 44 232 172168** of the Notified Body **TÜV NORD CERT GmbH (0044), Germany, 45141 Essen, Langemarckstrase 20.**

The manufacturer KENTAMED Ltd. maintain Technical File of the above-mentioned medical device for assurance and estimation its conformity.

**Place:** Kentamed Ltd., Plovdiv, Bulgaria

**Date:** 02.04.2018

**Signature:** .....

**Name:** Atanas Tashkov

**Title:** General Manager

