

# 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](mailto:sales@kentamed.com)

**Product:** Electrosurgical unit **KENTAMED 1ME**

**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

## **Additional information:**

The above-mentioned electrosurgical unit KENTAMED 1ME 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

