

DECLARATION OF CONFORMITY

№ 2/2018

Manufacturer: KENTAMED Ltd.

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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 RF100**

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 RF100** 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

