

## DECLARATION OF CONFORMITY

**Manufacturer's Name:** Th. Kazantzidis S.A. - MEDIPAC

**Manufacturer Address:** Industrial Area Kilkis, 611 00 Kilkis Greece

**Name of medical device:** Surgical Suture POLYAMID

Surgical Suture MONOMYD

**GMDN No:** 38000

**Categorization:** IIb - under rule 8 of Annex IX of Directive 93/42/EEC

The undersigned, declares that the non absorbable monofilament suture polyamide under the trade name POLYAMID, is according to the requirements of Directive 93/42/EEC and DY8d /1348/2004 of the Greek Ministry for Health and Social solidarity regarding distribution of medical devices.

We, at Th. Kazantzidis S.A. - MEDIPAC, also declare that the shelf life of POLYAMID suture is **5 years** and it should be stored **below 25°C** and away from direct heat and moisture.

This statement is supported by:

The EC declaration of conformity of quality system adopted by the EKAPTY, notified body, with identification number 0653. This statement is issued by the certificate (Number of Certificate: **301041049** Certificates expiration date: **24/05/2024**) and supersedes any previous statement has been issued for this product.

Date: 20/07/2021

Kazantzidis Themistoklis

Managing Director

**MEDIPAC - TH. KAZANTZIDIS S.A.**  
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