

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 Monofast (PGCL)

GMDN No: 16584

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

The undersigned, declares that the absorbable monofilament suture polycaprolactone under the trade name MONOFAST (PGCL), 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 Monofast (PGCL) suture is **2 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**, **301041049DE1** 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.
MEDICAL SUPPLIES
INDUSTRIAL AREA 61100 KILKIS, GREECE, P.O. BOX: 1
T: +30 23410 71991, F: +30 23410 71979
VAT: EL094148227 - GEMI: 014486935000