

## 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 MONOSORB (PDO)

**GMDN No:** 16584

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

The undersigned, declares that the absorbable monofilament suture polydioxanone under the trade name MONOSORB (PDO), 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 MONOSORB (PDO) 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**, **301041049DE2** 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  
IND. AREA 61100 KILKIS, GREECE, P.O. BOX: 1  
T.: +30 23410 71991, F.: +30 23410 71979  
VAT: EL094148227 - GEMI: 014486935000