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 SILK

Surgical Suture SEIDE

Surgical Suture SETA

GMDN No: 13910

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

The undersigned, declares that the non absorbable multifilament suture silk under the trade name SILK, 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 SILK 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.

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

Date: 20/07/2021

Kazantzidis Themistoklis

Managing Director