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 PROFIMED

Surgical Suture MONOSOFT

Surgical suture ELASYN

GMDN No: 13909

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

The undersigned, declares that the non absorbable monofilament suture Polytetrafluoroethylene under the trade name PROFIMED, 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 PROFIMED suture is **4 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, 301041049DE8*** 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

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