TH. KAZANTZIDIS SA – MEDIPAC
Industrial Area Kilkis
61100 Greece

Date: 17 May 2024

Confirmation Letter
Reference: GR_027637_2024_02

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, HTCert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2803 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

TH. KAZANTZIDIS SA – MEDIPAC
Industrial Area Kilkis
61100 Greece

SRN: GR-MF-000027637

Application ID: 27637_23_09
Application Date: 17/10/2023
Contract for MDR certification signed on 26/10/2023.

The devices covered by the formal application and the written agreement mentioned above are identified below. HTCert is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Filippos Kottis
Certification Director

Devices covered by this letter

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SILK Surgical Sutures Brand names: SILK / SEIDE / SETA	IIb	n/a	301041049 NB 0653
POLYAMID Surgical Sutures Brand names: POLYAMID / MONOMYD	IIb	n/a	301041049 NB 0653
POLYESTER Surgical Sutures	III	n/a	301041049, 301041049DE6 NB 0653
PROFIMED Surgical Sutures Brand names: PROFIMED / MONOSOFT / ELASYN	III	n/a	301041049, 301041049DE8 NB 0653
SURGICAL STEEL	IIb	n/a	301041049 NB 0653
SUPRAMID Surgical Sutures Brand names: SUPRAMID / SUPRAMYD	IIb	n/a	301041049 NB 0653

PROPYLEN Surgical Sutures	III	n/a	301041049, 301041049DE7 NB 0653
PGA Surgical Sutures	III	n/a	301041049, 301041049DE3 NB 0653
NEOSORB Surgical Sutures	III	n/a	301041049, 301041049DE4 NB 0653
NEOSORB RAPID Surgical Sutures	III	n/a	301041049, 301041049DE5 NB 0653
MONOSORB Surgical Sutures	III	n/a	301041049, 301041049DE2 NB 0653
MONOFAST Surgical Sutures	III	n/a	301041049, 301041049DE1 NB 0653

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/01	GR_027637_2024_01	Initial issue
2024/05/17	GR_027637_2024_02	· Addition of the surveillance undertaking under the applicable Directive. · Wording corrections in devices names.