ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

DATE: 30/05/23
REF. NUM.: 76886

Notified Body Statement Letter for audit surveillance of SIDAPHARM P.C., "SIDAPHARM"

To whom it may concern,

Confirmation of the status of an appropriate surveillance in the framework of Regulation EU 2023/607 of 15 March 2023 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, **EKAPTY**, a Notified Body (NB) designated against Medical Devices Directive (EU) 93/42/EEC (MDD) and identified by the number **0653** on NANDO, has provided a surveillance audit on 24/05/2023 for the extension of the validity of the certificate numbered **3050201023M** issued in accordance with Directive 93/42/EEC. Following the successful completion of the audit, the validity of the above certificate extends to 26/05/2024.

During the transitional period devices of the aforementioned certificate taking under notification the complementary confirmation letter (protocol number 10070/30/05/23) can lawfully be placed on the market by the condition that they are subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607).

On behalf of the Notified Body,

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