



EU DECLARATION OF CONFORMITY

Document number: ALGMP415101220801

Following the provisions of the medical device's regulation 2017/745(EU MDR).

We:

Legal Manufacturer

CV. Anggrek-Liar
Jalan Jomblang Barat 666 RT 09 RW 03
Kelurahan Candi, Kecamatan Candisari
Semarang 50257
Central Java
REPUBLIC OF INDONESIA

EU Authorized Representative

Kaio-Dia Europe Sasu
12, rue Bertrand
31480 Lagrault
Saint Nicolas, France

Single Registration Number (SRN)
ID-MF-000037819

Single Registration Number (SRN)
FR-AR-000037267

Manufacturing Sites

Anggrek-Liar / Kaio-Care
Jalan Tumpang IV No. 38
Kelurahan Bendan Ngisor
Kecamatan Gajahmungkur
Semarang 50233
Central Java
REPUBLIC OF INDONESIA

MAF Holding BV
Laan van Leeuwesteyn 62
2271 HL Voorburg, Nederland

Single Registration Number (SRN)
NL-AR-000044388

Declare under our sole responsibility for the universal device fixation support:

Kaio-Dia® Dia-Glucose Meter Pouch®
Non-Invasive Bag

Basic UDI-DI:
8994228UP-GM19T

Identification number:
See Appendix 1

SIGNATURE:

Date: 08 January 2025

Date of Issue :
Place of Issue : Semarang, Central Java, Indonesia
Name : Anik Susilawatiningsih
Function : Regulatory Affairs Manager

This Declaration of Conformity relating to Technical Documentation DOC415GMP71527 supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Dia® Dia-Glucose Meter Pouch®, a cases are independently developed as universal after market accessories used to ensures CGM can fit conviniently in one place and comes with compartement dedicates to diabetic medication and needs.

(see attachment **Appendix 1 – List of Supported Product Version #2)**

Dia-Glucose Meter Pouch® are available various design are non-sterile and may be reused (intended for single patient use only).

The devices are not designed or sold for use other than indicated.

EMDN code and description:

Z12040180 - GENERAL MEDICINE INSTRUMENTS FOR DIAGNOSIS AND MONITORING - HARDWARE

Class: I

Classification rule (Annex VIII): 1

to which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 (EU MDR).

This conformity is based on the following elements:

- Technical Documentation reference: DOC415GMP71527, of the product to which this declaration relates.

As a Class I medical device, this product is self-certified in accordance with Regulation (EU) 2017/745. The conformity assessment has been carried out under the sole responsibility of the manufacturer, without the involvement of a Notified Body.

The undersigned, acting on behalf of CV. Anggrek-Liar, assumes full responsibility for ensuring that the product complies with all applicable European laws and regulations.

SIGNATURE:

Date: 08 January 2025

Date of Issue :

Place of Issue :

Name :

Function :

Semarang, Central Java, Indonesia

Anik Susilawatiningsih

Regulatory Affairs Manager

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Appendix 1 – List of Supported Product

Date : 08-01-2025 Version #2

Producer	Product Name	
Accu-chek	Accu-Chek Active	
Smart care	Lancet needle	
Sensi	Alcohol Swab	

End of Document

SIGNATURE:

A handwritten signature in black ink, appearing to be 'Anik Susilawatiningsih'.

Date: 08 January 2025

Date of Issue :

Place of Issue :

Name :

Function :

Semarang, Central Java, Indonesia

Anik Susilawatiningsih

Regulatory Affairs Manager

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