



EU DECLARATION OF CONFORMITY

Document number: ALDBL725101240806

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 Lagraulet
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

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

Kaio-Dia® Dia-Body Pouch L©
Non-Invasive Belt

Basic UDI-DI:
8994228UP-BPL1B6

Identification number:
See Appendix 1

SIGNATURE:

Date: 06 August 2024

Date of Issue :

Place of Issue :

Name :

Function :

Semarang, Central Java, Indonesia

Anik Susilawatiningsih

Regulatory Affairs Manager

This Declaration of Conformity relating to Technical Documentation DOC725DBL89720 supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Dia® Dia-Body Pouch L©, a pouch are independently developed as universal after market accessories used to provide additional fixation support for a wide variety of automated insulin and medication on body delivery systems.

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

Dia-Body Pouch L© are available in various design and colors 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: DOC725DBL89720, of the product to which this declaration relates.

SIGNATURE:

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

Date: 06 August 2024

Date of Issue :

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Name :

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Anik Susilawatiningsih

Regulatory Affairs Manager

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Appendix 1 – List of Supported Product

Date : 06-08-2024 Version #1

Producer	Product Name	
Epipen	Epipen®	
Epipen	Epipen Jr.®	
Novo Nordisk	NovoRapid® Flexpen	
Novo Nordisk	NovoPen Echo®	
Novo Nordisk	NovoPen® 6	
Sanofi	Lantus SoloStar®	
Lilly	Humalog®	
Medtronic	Inpen™	

End of Document

SIGNATURE:

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