



EU DECLARATION OF CONFORMITY

Document number: ALDUB41510171572

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

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-Utility Belt®
Non-Invasive Belt

Basic UDI-DI:
8994228UA-UBA569

Identification number:
See Appendix 1

SIGNATURE:

Date: 14 January 2025

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 DOC415DUB71572 supersedes the previous Declaration signed 01-December-2021.

Intended Purpose:

Kaio-Dia® Dia-Utility Belt®, a multi purpose belt 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 #3**)

Dia-Utility Belt® are available in two adjustable sizes and 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: DOC415DUB71572, 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: 14 January 2025

Date of Issue :

Place of Issue : Semarang, Central Java, Indonesia

Name : Anik Susilawatiningsih

Function : Regulatory Affairs Manager

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Appendix 1 – List of Supported Product

Date: 14-01-2025 Version number #3

Producer	Product Name	
Kaio-Dia	Dia-Mini Pouch S	
Kaio-Dia	Dia-Mini Pouch U	
Kaio-Dia	Dia-Mini Pouch Lace	
Kaio-Dia	Insulin Pump Case Vertical	
Kaio-Dia	Insulin Pump Case Horizontal	

End of Document

SIGNATURE:

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

Date: 14 January 2025

Date of Issue :

Place of Issue :

Name :

Function :

Semarang, Central Java, Indonesia

Anik Susilawatiningsih

Regulatory Affairs Manager

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