



## **EU DECLARATION OF CONFORMITY**

Document number: ALWB378101220422

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® WaistBand®**  
Non-Invasive Waist-band

**Basic UDI-DI:**  
8994228UA-1WB3B

**Identification number:**  
See Appendix 1

**SIGNATURE:**

Date: 06 July 2024

**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 DOC378WB60224 supersedes the previous Declaration signed 01-December-2021.



### Intended Purpose:

Kaio-Dia® Dia-Waist Band®, a waist band are independently developed as universal after market accessories used to provide additional fixation support for a wide variety of medical devices, such as CGM and insulin patch pump, that in their native forms are attached to the skin with an adhesive fixation.

(see attachment **Appendix 1 – List of Supported Product version #3**)

Dia-Waist Band® are available in pediatric and adult sizes 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: DOC378WB60224, of the product to which this declaration relates.

**SIGNATURE:**

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

Date: 06 July 2024

**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 06-07-2024 version #003

| Producer    | Product Name      |  |
|-------------|-------------------|--|
| Abbot       | Freestyle Libre 2 |  |
| Abbot       | Freestyle Libre 3 |  |
| DexCom, Inc | Dexcom G6         |  |
| DexCom, Inc | Dexcom G7         |  |
| Insulet     | Omnipod 5         |  |
| Insulet     | Omnipod Dash      |  |
| Medtrum     | EasySense 7.1     |  |
| Menarini    | GlucoMen Day CGM  |  |
| Menarini    | GlucoMen Day Pump |  |
| Medtronic   | Guardian sensor 3 |  |
| Medtronic   | Guardian sensor 4 |  |
| Sibionics   | Sibionics GS1 CGM |  |

*End of Document*

**SIGNATURE:**



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