



EU DECLARATION OF CONFORMITY

Document number: ALABA333101220208

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

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

Kaio-Dia® Dia-Band Night & Day®
Non-Invasive Arm Sleeves

Basic UDI-DI:
8994228UA-ABA12-NDW4

Identification number:
See Appendix 1

SIGNATURE:

Date: 01 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 DOC333ABA56272 supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Dia® Dia-Band Night & Day®, arm sleeves 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-Bands Night & Day® are available in adult sizes and several color 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: DOC333ABA56272, of the product to which this declaration relates.

SIGNATURE:

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

Date: 01 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 01-07-2024 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:



Date: 01 July 2024

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