EU DECLARATION OF CONFORMITY

Document number: ALABL313101220203

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

We:

Legal Manufacturer	EU Authorized Representative
CV. Anggrek-Liar Jalan Jomblang Barat 666 RT 09 RW 03 Kelurahan Candi, Kecamatan Candisari Semarang 50257 Central Java REPUBLIC OF INDONESIA	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-Band Spacy Lacy©
Non-Invasive Arm Sleeves

Basic UDI-DI:
8994228UA-ABA12L8E

Identification number:
See Appendix 1

SIGNATURE: 

Date: 04 December 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 DOC313ABL35413 supersedes the previous Declaration signed 01-December-2021.

Intended Purpose:

Kaio-Dia® Dia-Band Sapcy Lacy©, 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 Spacy Lacy© are available in adult sizes and various 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: DOC313ABL35413, 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: 04 December 2024

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Function : Regulatory Affairs Manager

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Appendix 1 – List of Supported Product

Date 04-12-2024 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	
Medtronic	The Simplera™	
Sibionics	Sibionics GS1 CGM	

End of Document

SIGNATURE: 

Date: 04 December 2024

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