



EU DECLARATION OF CONFORMITY

Document number: ALDSDSE509101220322

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

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-Style® Enlite
Non-Invasive Arm Band

Basic UDI-DI:
8994228UA-SE254DDZ

Identification number:
See Appendix 1

SIGNATURE:

Date: 13 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 DOC509DSE72333 supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Dia® Dia-Style®, an arm band are independently developed as universal after market accessories used to provide additional fixation support for Enlite Diabetes sensor 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-Style® 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: DOC509DSE72333, 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:

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

Date: 13 December 2024

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 13-12-2024 version #3

Producer	Product Name	
Medtronic	Enlite™	

End of Document

SIGNATURE:

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

Date: 13 December 2024

Date of Issue :

Place of Issue :

Name :

Function :

Semarang, Central Java, Indonesia

Anik Susilawatiningsih

Regulatory Affairs Manager

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