



EU DECLARATION OF CONFORMITY

Document number: ALDBE744101250106

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

We:

Legal Manufacturer	EU Authorized Representatives
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 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-Body Pouch E©
Non-Invasive Pouch

Basic UDI-DI:
8994228UP-BPE1PFU

Identification number:
See Appendix 1

SIGNATURE:

Date: 17 January 2025

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 DOC744DBE91129 supersedes the previous Declaration signed 01-December-2021.

Intended Purpose:

Kaio-Dia® Dia-Body Pouch E®, a pouch 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-Body Pouch E® are available in various design and colors 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: DOC744DBE91129, 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: 17 January 2025

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Name : Anik Susilawatiningsih

Function : Regulatory Affairs Manager

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Appendix 1 – List of Supported Product

Date 17-01-2025 version #003

Producer	Product Name	
Medtronic	Minimed™ 630g	
Medtronic	Minimed™ 770g	
Medtronic	Minimed™ 780g	
Tandem	T:slim X2™	
Ypsomed	Mylife™ YpsoPump®	
SOOIL	Diabecare DANA-i	
SOOIL	Dana Diabecare RS	
SOOIL	Dana Diabecare R	

End of Document

SIGNATURE:



Date: 17 January 2025

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Place of Issue :

Name :

Function :

Semarang, Central Java, Indonesia

Anik Susilawatiningsih

Regulatory Affairs Manager

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