



EU DECLARATION OF CONFORMITY

Document number: ALDBB725101240801

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
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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-Body Pouch B®
Non-Invasive Belt

Basic UDI-DI:
8994228UP-BPB1A8

Identification number:
See Appendix 1

SIGNATURE:

Date: 01 August 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 DOC725DBB89188 supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Dia® Dia-Body Pouch B®, 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 #1**)

Dia-Body Pouch B © 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: DOC725DBB89188, of the product to which this declaration relates.

SIGNATURE:

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

Date: 01 August 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 : 01-08-2024 Version #1

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:

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