EU DECLARATION OF CONFORMITY

Document number: ALSB309101250221

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 SARL 661, route de Grisolles 82600 Aucamville 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-Care® Kaio-Shoulder Belt©
Non-Invasive Pouch

Basic UDI-DI:
8994228UP-PSBCS

Identification number:
See Appendix 1

SIGNATURE: 

Date: 21 February 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 DOC309SB73170 supersedes the previous Declaration signed 01-December-2021.

Intended Purpose:

Kaio-Care® Kaio-Shoulder Belt©, an alternative stylish and easy option to carry Kaio-Medication Pump Devise Bag H© and Kaio-Medication Pump Devise Bag V©. Strong and adjustable weebing to ensure comfort.

(see attachment **Appendix 1 – List of Supported Product version #1**)

Kaio-Shoulder Belt© are available in black 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: DOC309SB73170, 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: 21 February 2025

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 : 21-02-2025 Version #1

Producer	Product Name	
Kaio-Dia	Kaio-Medication Pump Devise Bag H	
Kaio-Dia	Kaio-Medication Pump Devise Bag V	

End of Document

SIGNATURE:

Date: 21 February 2025

Date of Issue :
Place of Issue : Semarang, Central Java, Indonesia
Name : Anik Susilawatiningsih
Function : Regulatory Affairs Manager

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