



EU DECLARATION OF CONFORMITY

Document number: ALZB275101220722

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-Zipper Bag®
Non-Invasive Bag

Basic UDI-DI:
8994228UB-ZB16X

Identification number:
See Appendix 1

SIGNATURE:

Date: 19 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 DOC275ZB36281supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Dia® Dia-Zipper Bag®, a spacious cases are independently developed as universal after market accessories used to ensures all daily need of can fit conviniently in one place and comes with compartement dedicates to diabetic medication and needs.

(see attachment **Appendix 1 – List of Supported Product Version #3**)

Dia-Zipper Bag® are available in various design adn 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: DOC275ZB36281, 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:

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Semarang, Central Java, Indonesia

Anik Susilawatiningsih

Regulatory Affairs Manager

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Appendix 1 – List of Supported Product

Date : 19-12-2024 Version #3

Producer	Product Name	
Alcohol swap	Alcohol swap	
Roche Diabetes Care, Inc.	Accu-chek Lancet Needle	
Roche Diabetes Care, Inc.	Accu-chek softclick	
Roche Diabetes Care, Inc.	Accu-chek Active	
Abbott	FreeStyle Lite	
Abbott	FreeStyle Libre CGM	
Dextro Energy GmbH & Co	Dextro Glucose tablet	
Lancet Device Pen	Lancet Device Pen	

End of Document

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