



EU DECLARATION OF CONFORMITY

Document number: ALPICK477101250219

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 Representatives

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

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-Care® Kaio-PICC Cover Kids®
Non-Invasive Arm Sleeves

Basic UDI-DI:
8994228UA-PCJ118R

Identification number:
See Appendix 1

SIGNATURE:

Date: 10 February 2025

Date of Issue :

Place of Issue :

Name :

Function :

Semarang, Central Java, Indonesia

Anik Susilawatiningsih

Regulatory Affairs Manager

This Declaration of Conformity relating to Technical Documentation DOC477PICK76195 supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Care® Kaio-PICC Cover®, an arm sleeves are independently developed as universal after market accessories used to provide additional support and coverage for a wide variety of PICC line in style without interfering with the PICC Line function itself.

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

Kaio-PICC Cover® are available in many design and color 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: DOC477PICK76195, 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: 10 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 10-02-2025 version #1

Producer	Product Name	
VYGON	Premicath	
Cardinal Health	Argyle™ Neonatal PICC lines	
Health Line Medical Products	Synergy XS CT PICC™ line	
Neo Medical Inc.	NeoMagic® line	
First Medical Company	Pediatric Vascul-Picc TLS	

End of Document

SIGNATURE:

Date: 10 February 2025

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Function :

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Anik Susilawatiningsih

Regulatory Affairs Manager

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