



EU DECLARATION OF CONFORMITY

Document number: ALTCK432101250203

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 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-Tube Covers Kids®
Non-Invasive Patch

Basic UDI-DI:
8994228KT-GTCJ1EP

Identification number:
See Appendix 1

SIGNATURE:

Date: 03 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 DOC532TCK94861 supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Care® Kaio-Tube Covers®, are a covers used to absorb leakage from the stoma site, prevent skin irritation from gauze/tape, provide a soft barrier, keep the tube secure, and offer discretion, helping manage gastrostomy, jejunostomy, and other feeding tubes for comfort, hygiene, and dignity during daily activities, sleep, and travel.

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

D Kaio-Tube Covers® 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: DOC532TCK94861, 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: 03 February 2025

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 : 03-02-2025 Version #1

Producer	Product Name	
Avanos Medical	MIC-KEY*G Feeding Tubes	
Applied Medical Technology (AMT)	MiniONE® Capsule Monarch® G-Tube	
Applied Medical Technology (AMT)	G-JET® Gastro Jejunal	
Cardinal Health	Kangaroo™ Gastrostomy Feeding Tubes	
Boston Scientific	PEG (Percutaneous Endoscopic Gastrostomy) EndoVive™	
Vygon	Feeding tubes	
NuFlo™	Polyurethane gastrostomy tube	
Cook Medical	Entuit® feeding tube	
danumed Medizintechnik GmbH	danumed® GastroTube	

End of Document

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