



EU DECLARATION OF CONFORMITY

Document number: ALNGT532101260105

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

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-Nasogastric Tape®
Non-Invasive Tape

Basic UDI-DI:
8994228UP-NTCJ

Identification number:
See Appendix 1

SIGNATURE:

Date: 05 January 2026

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 DOC532NGT95356 supersedes the previous Declaration signed 01-December-2021.



Intended Purpose:

Kaio-Care® Nasogastric Tape®, a breathable, soft, flexible and skin-friendly non-woven patch that designed to secure nasogastric (NG) tubes, feeding tubes, and oxygen tubing in place while minimizing skin irritation. The patch offers a firm hold through workouts, showers, and daily wear. The printing and cutting process did not alter the patches function.

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

Kaio-Care® Nasogastric Tape®, are available in various colors and design are non-sterile and 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: DOC532NGT95356, 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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Appendix 1 – List of Supported Product

Date: 05-01-2026 Version number #1

Producer	Product Name	
Fresenius Kabi	Freka® Gastric Feeding Tubes	
Fresenius Kabi	Freka® Enteral Feeding Tubes	
Cardinal Health	Kangaroo	
OneMed	Oxyflow	
Salter Labs	Green Crush-Resistant Tubing	

End of Document

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