



EU DECLARATION OF CONFORMITY

Document number: ALHN426101220512

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 Lagraulet
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-Harness for Night®
Non-Invasive Harness

Basic UDI-DI:
8994228UA-HKN15S

Identification number:
See Appendix 1

SIGNATURE:

Date: 09 January 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 DOC426HN69876 supersedes the previous Declaration signed 01-December-2021.

Intended Purpose:

Kaio-Dia® Dia-Harness for Night®, a harness are independently developed as universal after market accessories used to provide additional fixation support for a wide variety of automated insulin and medication on body delivery systems.

(see attachment **Appendix 1 – List of Supported Product version #2**)

Dia-Harness for Night® are available in pediatric sizes 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: DOC426HN69876, 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: 09-01-2025 Version number #2

Producer	Product Name	
Medtronic	Minimed™ 630g	
Medtronic	Minimed™ 770g	
Medtronic	Minimed™ 780g	
Tandem	T:slim X2™	
Ypsomed	Mylife™ YpsoPump®	
SOOIL	Diabecare DANA-i	
SOOIL	Dana Diabecare RS	
SOOIL	Dana Diabecare R	
SOOIL	Dana Diabecare IIS	

End of Document

SIGNATURE:



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Function :

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Anik Susilawatiningsih

Regulatory Affairs Manager

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