

Declaration of Conformity

(2014/53/EU)

Type of Product: Ambulatory insulin infusion administration unit/remote control system
(GMDN 63866)

Model	Components	Serial/Lot Numbers Covered by This DoC		Version
		Lot Number	Serial Number	Hardware Version:
GlucoMen Day PUMP	Patch (IDU200A)	JP1YMnnn(Total 8 digits)* *JP1 = Model short code YM = Y: 0~z / M: 1 ~ C nnn = given number by lot sequence	JP1nnnnnnn(Total 11 digits)* *JP1 = Model short code nnnnnnnn(8 digits) = Serial number	V 2.5 Software Version: V 1.0.2
	ADM (IL100A)	JA1YMnnn(Total 8 digits)* *JA1 = Model short code YM = Y: 0~z / M: 1 ~ C nnn = given number by lot sequence	JA1nnnnnnn(Total 10 digits)* *JA1 = Model short code nnnnnnn(7 digits) = Serial number	V 2.8 Software Version: V 1.0.2

Company: EOFlow Co., Ltd.
H2202, Healthcare Innovation Park, 172, Dolma-ro, Bundang-gu, Seongnam-si,
Gyeonggi-do, Republic of Korea

The product mentioned above complies with the essential requirements and other relevant provisions of Directive 2014/53/EU, when used for its intended purpose:

Safety & Health (Article 3.1 a)	IEC 60601-1:2012 IEC 60601-2-24:2012 EN 62479:2010
Electromagnetic Compatibility (Article 3.1b)	IEC 60601-1-2:2014 ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4
Radio Spectrum Efficiency (Article 3.2)	ETSI EN 300 328 V2.2.2

Conformity assessment route: Annex II applied Directive 2014/53/EU

Declaration Statement:

We hereby declare under our sole responsibility that the products are in conformity with Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) relating to the making available on the market of radio equipment.

Date of Issue: 09 / SEP / 2021
Name: KyoungSoo, KIM
Function: Quality Management Representative
Signature: 

