EC Declaration of Conformity

DoC No.	SDoC-G-F-2601-001
Revision	A

This declaration of conformity is issued under the sole responsibility of **Sky Labs Inc**. We ,hereby, declare that the medical device(s) specified below meets the provisions of Regulation **(EU) MDR 2017/745** on medical devices and comply with any other relevant Union legislation **(RoHS Directive 2011/65/EU, Radio Equipment Directive 2014/53/EU)** that provides for the issuing of an EU declaration of conformity.

All supporting documentation is retained at the premises of the manufacturer.

Manufacturer	**Name**	:	Sky Labs Inc.
	Trademark	:	SkyLabs
	Address	:	#702, #703, 58, Pangyo-ro 255beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
	Actor ID/SRN	:	KR-MF-000026801
Authorized Representative	**Name**	:	Obelis s.a.
	Address	:	Boulevard Général Wahis 53. B-1030 Brussels, Belgium
	Actor ID/SRN	:	BE-AR-000000106
Basic UDI DI		:	88000826SLCDQZ
Name of the Device (s)		:	BLOOD PRESSURE MONITORING INSTRUMENTS
Model name(s)		:	CART BP pro (Model Name: CART-RING and CART-CRADLE)
Intended Use		:	CART BP pro is a non-invasive ambulatory blood pressure monitoring device. It is intended for measuring systolic/diastolic blood pressure and pulse rate in adults under the supervision of a healthcare professional.
Product code (EMDN code)		:	Z12030203
Classification		:	Class IIa (EC conformity declaration according to annex VIII Rule 10)
Notified Body	**Name**	:	DNV Product Assurance
	Address	:	Veritasveien 1, 1363 Høvik, Norway
	Identification number	:	2460
Conformity assessment procedure		:	Chapters I and III of Annex IX
MDR Certificate		:	Certificate ID, Issue date

CE 2460

Signed By

Name / Position : Jack Lee / CEO

Date of issued : 02 / Oct. / 2026

Place : Republic of Korea

Attachment to declaration of conformity [CART BP pro (Model Name: CART-RING and CART-CRADLE]

UDI-DI	Model number	Compatible models	
		CART-RING	CART-CRADLE
(01)08800082601032	SL-MPD2K07E	SL-MRA2K07	SL-MCA2K07
(01)08800082601049	SL-MPD2K08E	SL-MRA2K08	SL-MCA2K08
(01)08800082601056	SL-MPD2K09E	SL-MRA2K09	SL-MCA2K09
(01)08800082601063	SL-MPD2K10E	SL-MRA2K10	SL-MCA2K10
(01)08800082601070	SL-MPD2K11E	SL-MRA2K11	SL-MCA2K11
(01)08800082601087	SL-MPD2K12E	SL-MRA2K12	SL-MCA2K12
(01)08800082601094	SL-MPD2K13E	SL-MRA2K13	SL-MCA2K13