

## EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

## Full Quality Assurance System

## Certificate Number

CE-MDD-0116/05/2021/01

**Manufacturer** : WUHAN UNION BIO-MEDICAL TECHNOLOGY CO.,LTD.

**Address** : BLD23 NO.5(1)DONGXIHU ROAD NO.5647 DONGXIHU DISTRICT WUHAN CITY,HUBEI,CHINA

**Product(s)** : Vital Signs Monitor  
Software Version: V.1.40

**Model(s)** : Please see 2<sup>nd</sup> page for details of product.

**Report Number** : CE-MED-0116

**First Issue Date and Place** : 2021.05.10 & Istanbul

**Revision Number and Date** : 00 / --

**Validity Date** : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vicdan Akdağ  
Chairman



**NOTİCE BELGELENDİRME  
MUAYENE VE DENETİM  
HİZMETLERİ A.Ş.**

Esentepe Mahallesi Milangaz Caddesi  
No:75/A/92 Kartal / İstanbul/TÜRKİYE  
www.notice.com.tr

Product Name	Model Name	Specifications
Vital Signs Monitor	PC100	NIBP
		SpO2
		TEMP
	PC100PRO	NIBP
		TEMP
	PC100SE	NIBP
		SpO2
	PC100S	TEMP
		SpO2

