

Software Justification

Software type:

1. Embedded software : software that is installed within medical device hardware.

2. Stand alone software as:

- Web-based application: work with Web browser such as Google Chrome, Firefox, Microsoft Edge without installation
- Application: require installation including Home use or Professional use

	Product/Software (intended use)	Product Type		Risk Class		Remark
		Non medical device	Medical device	Rule	Class	
1	Vital Sign					
1.1	Blood Pressure		●	10 (1)	2	
1.2	Body temperature		●	11 (1)	3	for medical diagnostics
	Body temperature	●				for safety purpose
1.3	Heart rate, Pulse rate					
(1)	Exercise Heart rate during exercise	●				for physical fitness test
(2)	Exercise Stress test (EST)		●			for medical purpose
(3)	Electrocardiogram : EKG or ECG		●	10 (1)	2	ECG: Sinus or AFib
(4)	Irregular Rhythm Notification Feature (IRNF)		●	11 (1)	3	Atrial Fibrillation (AFib)
1.4	Respiratory rate, Oxygen saturation/SpO2 ? Pulse O2)					
(1)	For sport activities or travelling	●				
(2)	Hyperxemis assessment		●			
1.5	The maximum volume of oxygen (VO2 max)					
(1)	Performance of heart, blood vessel, lung and muscle by exercise test	●				
(2)	Diagnose heart disease and artery and lung disease by measure, analyse and interpret the O2 metabolism rate during exercise		●			
1.6	Blood Glucose					
1.7	Measurement of body fat, body fluid (Bioimpedance)	●				
2	Sleeping					
2.1	Deep Sleep	●				
2.2	Sleep Apnea		●	10 (1)	3	
2.3	Sleep behavior	●				
3	Mental Health					
3.1	Stress screening test	●				
3.2	Depression test	●				
3.3	Suicide risk screening	●				statistic calculation from questionnaires

3.4	Mental Health assessment	●				
3.5	Concentration, breathing, emotion exercise	●				to control stress level
3.6	Happiness level measurement	●				
3.7	Emotional Quotient : EQ assessment	●				
3.8	Dementia level measurement		●	10 (1)	3	Analysis/monitoring
4	Fall detection					
4.1	Fall detection while walking	●				in the hospital/home
4.2	Fall detection while sleeping	●				in the hospital/home
5	Perception deficiency					
5.1	Visual impairment					
	Fundus Photography or Fundus Camera		●	10 (1)	2	
	Vision measurement devices		●	12	1	
5.2	Hearing impairment		●	10 (1)	2	
5.3	Learning disorder (LD)/Learning disability		●	10 (1)	2	
6	Risk Assessment					
6.1	Disease risk prediction	●				
6.2	Risk area assessment	●				
7	Planning					
7.1	Treatment plan	●	●	10 (1)	2	
7.2	Meals and exercise plan	●				
8	Alarm/ Notification					
8.1	Alarm for daily activities	●				
9	Service					
9.1	Medicine recommendation	●				
9.2	Robot for medicine management	●				
9.3	Area or vehicle for medical services	●				
9.4	Telemedicine	●				
9.5	Remote medicine service system	●				
9.6	Medical operations software	●				software used in medical facilities for operation management, healthcare record, patient appointment and service fee/payment system
10	Medical Software					
10.1	Software for storage and transfer of patient medical data		●	12	1	
10.2	Software for Diabetic Retinopathy screening		●	10 (1)	3	
10.3	Software for medical diagnostics on stroke/heart disease treatment		●	10 (1)	3	
10.4	Software for monitoring defibrilators		●	9 (2)	3	
10.5	Software for monitoring the important parameters of the patient during cardio surgery		●	10 (1)	3	
11	Chatbot for messaging application by automatic responses	●				