EC Declaration of Conformity

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Proposed Scope :

93/42/EEC–(Annex Ⅱ (excluding section 4)) – CE1639	**Infrared forehead thermometer (Model : FS-700, HFS-700, HFS-1000) Nasal Aspirators(Model:HNA-200, HNA-300, HNA-1000)**
93/42/EEC – (Annex V) – CE1639	**Blood pressure monitor(Model:HBP-500, HBP-700, HBP-1520)**
ISO 13485:2016 - UKAS	**Design, development and manufacture of infrared thermometers, blood pressure monitor and nasal aspirators**

The manufacturer is exclusively responsible for declaration of conformity.

Declares that the medical device described hereafter,

Product name:	**Infrared Skin Thermometer**
Model Name:	**HFS-1000**
UMDNS CODE:	**14036 [Thermometers, Infrared]**
Classification:	**Class Ⅱa(Annex Ⅸ Rule10)**

Noted product is in conformity with technical requirements and applicable regulations:

Directive:	**93/42/EEC amended by MDD 07/47/EC**
Standards:	**EN 60601-1:2006**
	EN 60601-1-6:2010
	EN 60601-1-11:2010
	ISO 80601-2-56:2017
	EN 60601-1-2:2015
	EN 1041:2008
	EN ISO 15223-1:2016
Notified Body:	**SGS Belgium NV**
	Noorderlaan 87, BE-2030 Antwerpen, Belgium
	Notified Body Number 1639

This product is classified as Class Ⅱa, Council Directive 93/42/EEC, Annex IX, Rule 10, and complies with the requirements and regulations of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

Date of issued: March 9th 2021

JAE-HO SHIN

PRESIDENT

on behalf of HuBDIC Co.,Ltd.