DECLARATION OF CONFORMITY

CE

Name of company: CINCON ELECTRONICS CO., LTD.

Address:

No. 8-1 Fu Kung Rd. Fu Hsing Industrial Park, Fu Hsing Hsiang,

Chang Hua Hsien, Taiwan, R.O.C.

Declares that the product

Open Frame

CFM21MX-Y (X can be 050, 090, 120, 150, 240;

-Y can be blank, -E, -T or -S)

referred to this declaration conforms with the standard(s) or directive(s) as far as applicable:

Product Safety Standard:

EN60601-1: 2006+A11+A1+A12

EMC Standards

EN61204-3: 2000 (Class B, Low severity levels)

EN60601-1-2: 2015 (Group 1, Class B,

HOME HEALTHCARE ENVIRONMENT)

EN61000-6-1: 2007

EN61000-6-3: 2007+A1: 2011+AC: 2012 EN55011: 2009 +A1:2010 (Group 1, Class B)

EN55022: 2010+AC: 2011 (Class B) EN55032: 2015+AC: 2016 (Class B)

EN55024: 2010+A1: 2015

EN61000-3-2: 2014 EN61000-3-3: 2013

Directives

93/42/EEC (Medical Device Directive)

This product must be used within other equipment and must not operated as a stand alone product.

The company named above will keep on file for review the following technical documentation:

- · Technical drawings
- ·Other technical documentation

Manufacturer

Signature: Johnson cheng

Name: Johnson Cheng / President

Date: Nov. 01. 2017