

DECLARATION OF CONFORMITY

Manufacturer:

HEALTH & LIFE CO., LTD,

9F, No.186, Jian Yi Road, Zhonghe District
23553, New Taipei City, Taiwan

Whose single Authorized Representative:

EMERGO EUROPE

Prinsessegracht 20, 2514 AP The Hague,
The Netherlands

We, **HEALTH & LIFE CO., LTD.**, as the supplier of **Seagull Aps** hereby declare that the products

Medical device:	Electronic Blood Pressure Monitor
Classification (MDD Annex IX)	Class IIa
Product Model:	HL858DK HL168KD (Seagull Aps's model: S-168KD) HL868ED (Seagull Aps's model: S-868ED)

are in full compliance with the Essential Requirement listed in the Annex I and Class IIa under Rule 10 according to Annex IX of the European Medical Device 93/42/EEC (MDD).

This declaration of conformity is supported by TUV Rheinland LGA GmbH, notified body Number 0197, with a Certificate, Registration No.: HD 60132365 0001, with reference to Annex II of the MDD.

The products mentioned above also are in full compliance with the standards listed below:

Applied Standard:

EN ISO 15223-1	EN ISO 13485	EN 1041+A1
EN ISO 10601-1+A2	EN 1060-3	EN ISO 81060-1
EN 1060-4	EN ISO 10993-1/AC	EN ISO 10993-5
EN ISO 10993-10	EN ISO 14155	EN ISO 14971
EN 15986	EN 60601-1/A1	EN 60601-1-2
EN 62304/AC	EN 60601-1-6	EN 60601-1-11
EN 62366-1+A1		

The above-mentioned declaration of conformity is exclusively under the responsibility of **HEALTH & LIFE CO., LTD.**

Taipei, Jan. 28, 2021

Place and Date of issue



Name, Signature and Position of manufacturer

President, Albert Lee

EC Declaration of Conformity

Manufacturer:

HEALTH & LIFE CO., LTD,

9F, No.186, Jian Yi Road, Zhonghe District 23553

New Taipei City, Taiwan

Whose single Authorized Representative:

EMERGO EUROPE B.V.

Prinsessegracht 20, 2514 AP The Hague, The

Netherlands

We, **HEALTH & LIFE CO., LTD.**, as the supplier of **Seagull Aps** hereby declare that the products

Medical device:	Electronic Blood Pressure Monitor
Classification (MDD Annex IX)	Class IIa
Product Model:	HL868BF (Seagull Aps's model: S-868BA) HL888HA (Seagull Aps's model: S-888HA) HL168KD (Seagull Aps's model: S-168KD) HL868ED (Seagull Aps's model: S-868ED)

are in full compliance with the Essential Requirement listed in the Annex I and Class IIa under Rule 10 according to annex IX of the European Medical Device Directive 93/42/EEC (MDD). This declaration of conformity is supported by TÜV Rheinland LGA Products GmbH, notified body Number 0197, with a Certificate, Registration No.: HD 60132365 0001, with reference to Annex II of the MDD.

The products mentioned above also are in full compliance with the standards listed below:

Applied Standard:

EN ISO 15223-1:2016	EN ISO 13485:2016	EN 1041:2008
EN 1060-1:1995+A2:2009	EN 1060-3:1997+A2:2009	EN ISO 81060-1:2012
EN 1060-4:2004	EN ISO 10993-1:2009 /AC:2010	EN ISO 10993-5:2009
EN ISO 10993-10:2010	EN ISO 14155:2011	EN ISO 14971:2012
EN 15986:2011	EN 60601-1:2006/A1:2013	EN 60601-1-2:2015
EN 60601-1-4:1996/A1:1999	EN 60601-1-6:2010	EN 60601-1-11:2010
EN 62304:2006/AC:2008	EN 62366:2008	

The above-mentioned declaration of conformity is exclusively under the responsibility of HEALTH & LIFE CO., LTD.

Taipei, Feb. 12, 2019

Place, date



Legally binding signature, Function

Chairman, Paul Yang