ISO 13485 CE FDA

Spirit®
SINCE 1975

DECLARATION OF CONFORMITY

DECLARES that the sanitary products (**Stethoscopes as follows**)

CK-M600P/600PF	CK-S601PF/B	CK-AC603PY	CK-625P	CK-S746PF
CK-M600CPF	CK-S601PF/C	CK-AC603LB	CK-S621P/S621PF	CK-SS747P/SS747PF
CK-M600GPF	CK-S601PF/R	CK-AC60FG	CK-638PF	CK-S747PF/R
CK-M601P/M601PF	CK-S601PF/S	CK-AD606PF	CK-638DPF	CK-S747T
CK-M601CPF	CK-SS601PF	CK-MA603CP	CK-638CPF	CK-A747PF
CK-M601DP	CK-SS601CPF	CK-604P/M604P	CK-638GPF	CK-S747CPF
CK-M601GPF	CK-SD601PF	CK-A604T	CK-648PF	CK-S747GPF
CK-MA601CP	CK-SD601CPF	CK-605P	CK-648CPF	CK-SS747P/SS747PF
CK-601P/601PF	CK-S601P/S601PF	CK-A605T/A605CP	CK-648GPF	CK-SS747CPF
CK-601CP/601CPF	CK-603P	CK-M606PF	CK-649	CK-SS747PF/R
CK-T601P	CK-603PW	CK-S606P/S606PF	CK-649C	CK-S748PF
CK-A601DP	CK-A603T	CK-S607P	CK-649G	CK-S748GPF
CK-A601SDP	CK-A603CP	CK-608T	CK-701	CK-749PF
CK-A601GDP	CK-AC603D	CK- M615PF	CK-715PF	CK-703
CK-CU601PF	CK-AC603H	CK-M615CPF	CK-715CPF	CK-S751PF
CK-CU606PF	CK-AC603P	CK-M615PF/B	CK-715PF/B	CK-S757PF
CK-F601PF	CK-AC603R	CK-M625PF	CK-725PF	CK-SS757PF
CK-F606PF	CK-AC603S	CK-M625CPF	CK-725CPF	CK-SS757CPF
CK-F606DPF	CK-AC603K	CK-M625PF/B	CK-725PF/B	

Classification of the Product: Class I
The conformity assessment complies with the Annex VII and meets the Annex I of 2017/745 as amend by 2007/47/EC of the following harmonized standards:

EN ISO 15223-1: 2016 **EN 1041: 2008+A1: 2013** **EN ISO 14971: 2019**

which applies to them, and therefore assures the absence any endangering of the health and safety of persons, provided the that product is used for its envisaged purpose, as well as offering the qualities assigned to it. UNDERTAKES to establish and to keep up to date a systematic procedure to review the experience acquired with the production the phase after production, using the opportune means to apply the necessary corrective measures, and also UNDERTAKES to inform the competent authorities as to the following situations as soon as they become known:

a) Any defective functioning or alteration of the characteristics of its features, as well as any inadequacy of the labeling or instructions for the use of the product which could give rise to or may have caused death or severe alteration of the state of health of a patient or of a user.

精國醫療器材有限公司
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SPIRIT MEDICAL CO., LTD.
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b) Any technical or sanitary reason, related with the characteristics or the features of a product, for the reasons indicated in the previous paragraph which may have led the manufacturer to systematically withdraw products of the same type from the market.

EU Authorized Representative : SKLEP DLA LEKARZA
ul sw. Szczepana 20a, 61-465 Poznan, POLAND

The following manufacturer is exclusively responsible for making this declaration:

Company Name: CHIN KOU MEDCIAL INSTRUMENT CO., LTD.
Address: 2nd FLOOR, NO. 68, SEC. 2, GUO DAO ROAD, LUZHOU DISTRICT, NEW TAIPEI CITY 24766, TAIWAN R.O.C.

(Place and date of Issue)
TAIPEI, TAIWAN
April 23, 2021

(Authorized person)

STEVEN YAN

精國醫療器材有限公司
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