



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Jiangsu Saikang Medical Equipment Co., Ltd.
Address: No. 35 Lehong Road, Modern Agriculture Demonstration Park, Zhangjiagang City, Jiangsu Province, China
SRN: CN-MF-000002228

EC Representative: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA
Capelleaan den IJssel, The Netherlands
SRN: NL-AR-000000247

Product Name: Stretcher
Model/Size: Refer to Annex
Intended Purpose: Stretchers are used to transport and move patients in medical institutions It used as hospital furniture for transporting and setting down and Treating patient.

Basic UDI-DI: 697453996StretcherWR

Classification: Class I
Rule: Rule 1(NON electric stretchers), Rule 13(electric stretchers), Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare, under our sole responsibility, that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following standards.

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|----------------------|--------------------------------------|
| EN ISO 14971: 2019 | EN ISO 15223-1: 2021 |
| EN ISO 20417:2021 | EN ISO 10993-1: 2020 |
| EN ISO 10993-5: 2009 | EN ISO 10993-10: 2013 |
| IEC 60601-1-2:2014 | IEC 60601-1:2005+AMD1:2012+AMD2:2020 |

It is also declared that the electric stretchers are in conformity with the Directive 2011/65 /EU and Directive (EU) 2017/2102 of the European Parliament and of the Council and Commission Delegated Directive (EU) 2015/863 on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment.

Signature: Bessie Wang Position: GM Date: July 1st, 2021 Place: Jiangsu / China

Annex

| | | | | | |
|-----------|--------------|--------------|--------------|--------------|------------|
| SKB037(A) | SKB037(B) | SKB037(C) | SKB038-2 | SKB038-4 | SKB039-101 |
| SKB039(A) | SKB039(B) | SKB039(C) | SKB039(C1) | SKB039(C2) | SKB039(C3) |
| SKB039(D) | SKB039(E) | SKB039(E)-1 | SKB039(F) | SKB039(G) | SKB039(H) |
| SKB039(K) | SKB040(A001) | SKB040(A002) | SKB040(A004) | SKB040(A006) | SKB040(A) |
| SKB040(B) | SKB040(E) | SKB041 | SKB041-1 | SKB041-2 | SKB041-3 |
| SKB041-3S | SKB041-6 | SKB1A01 | SKB1A01-1 | SKB1A01-2 | SKB1A02 |
| SKB1A02-1 | SKB1A03 | SKB1A04 | SKB1A05 | SKB1A06 | SKB1A07 |
| SKB1A08 | SKB1A09 | SKB1A10 | SKB1A11 | SKB1A12 | SKB1A13 |
| SKB1A14 | SKB1A15 | SKB2A01 | SKB2A02 | SKB2A03 | SKB2A04 |
| SKB2A04-1 | SKB2A05 | SKB2A06 | SKB2A07 | SKB2A08 | SKB2A09 |
| SKB2A09-1 | SKB2A10 | SKB2A11 | SKB2A11-1 | SKB2A12 | SKB2A13 |
| SKB2A14 | SKB3A001 | SKB3A001(1) | SKB3A002 | SKB3A005 | SKB3A006 |
| SKB3A101 | SKB3A102 | SKB3A103 | SKB3A104 | SKB1B01 | SKB1B01-1 |
| SKB1B02 | SKB1B02-1 | SKB1B03 | SKB1B04 | SKB2B01 | SKB2B02 |
| SKB2B03 | SKB2B04 | SKB2B05 | SKB2B07 | SKB1C01 | SKB1C01-1 |
| SKB1C02 | SKB1C02-1 | SKB1C02-2 | SKB1C03 | SKB1C04 | SKB1C05 |
| SKB1C05-1 | SKB1C05-2 | SKB1C06 | SKB1C07 | SKB1C08 | SKB1C09 |
| SKB1C09-1 | SKB1C11 | SKB1C12 | SKB2C01 | SKB2C02 | SKB2C03 |
| SKB2C04 | SKB3C01 | SKB3C02 | SKB3C03 | SKA-1A | SKA-2A |
| SKA-3A | SKA-4A | SKA-1B | SKA-2B | SKA-3B | SKA-4B |
| SKA-1C | SKA-2C | SKA-3C | SKA-4C | SKA-1D | SKA-2D |
| SKA-3D | SKA-4D | SKA-1E | SKA-1F | SKA-2F | SKA-3F |
| SKA-4F | SKA-1G | SKB-1A | SKB-2A | SKB-3A | SKB-4A |
| SKB-5A | SKB-6A | SKC-2B1 | SKC-2B2 | SKC-2B3 | SKC-1B1 |
| SKC-1B2 | SKC-3A9 | SKC-3B4 | SKC-3D4 | SKC-3D5 | SKC-3E4 |
| SKC-3E5 | SKC-3E8 | SKC-3E9 | SKC-3F5 | SKK-A | SKK-B |
| SKM-A | SKM-B | SKM-C | SKM-D | SKM-E | SKM-F |
| SKM-G | SKU-B1 | SKU-C1 | SKU-C2 | SKV-AC | SKV-AE |
| SKV-BC | SKV-BE | SKW-A1 | SKW-B1 | SKW-C1 | SKW-A2 |
| SKW-B2 | SKW-C2 | SKX-B1 | SKX-B2 | SKX-B3 | SKX-C1 |
| SKX-C2 | | | | | |
| SKB1C10 | | | | | |

Bessie Wang July 15th, 2021