



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 Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Product Name: Stretcher
Model/Size: Refer to Annex
Intended Use: 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), 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 harmonized standards.

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: 2023

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) 2017/2012 of the European Parliament and of the Council and Commission Delegated Directive (EU) 2015/863 on the restriction of the used of certain hazardous substances (RoHS) in electrical and electronic equipment.

Signature: BESSIE WANG Position: GM Date: APRIL 30, 2025 Place: Jiangsu / China

江苏赛康医疗设备股份有限公司

Jiangsu Saikang Medical Equipment Co., Ltd.

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	SKB1C10	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	SKB1C01-2	SKB2A15	SKB2A15-1	SKB2A16
SKB3A003	SKB3A204	SKB3A204-1	SKC-3B5	SKC-3B6	SKC-3B7
SKC-3B10	SKC-3C4	SKC-3C5	SKC-3C9	SKB040	SKB038

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SKB038-5

SKB041-4

SKB041-10

SKB041-12

SKB041-7

SKV-AD

SKV-BD

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江苏赛康医疗设备股份有限公司
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Ltd.