



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert GmbH

Harffstr. 47, 40591 Düsseldorf, Germany

SRN: DE-AR-000010869

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable 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

EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V0805030101-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: HEALTH SOURCE MEDICAL EQUIPMENT (GUANGDONG) LTD.

Address: No. 10 West Industrial Avenue, Haimai Industrial Zone, Gaohai Community, Danzao Town, Nanhai District, Foshan City, Guangdong Province, China

SRN: CN-MF-000039568

Product Information

Name: TRANSFER AID PATIENT LIFT

Model: XZY701, XZY702, XZY703, XZY704, XZY705, XZY706, XZY707, XZY708, XZY709

EMDN: V0805030101

Basic UDI-DI: /

Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Date: 2024.10.31

Position: GM

Place: Guangdong/China



STATE OF TEXAS

DEPARTMENT OF COMMERCE

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