



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Fascinatio Boulevard 522, Unit 1.7,  
2909VA Capelle aan den IJssel, The  
Netherlands  
SRN: NL-AR-000000247

## Conformity Assessment

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

### Applicable Standards

EN ISO 15223-1: 2021  
EN ISO 20417:2021  
EN ISO 14971:2019  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2023  
EN ISO 10993-23:2021  
EN 12183:2022

### Remark

The declaration of conformity is valid in connection  
with the release technical document  
CE-MDR-TCF002.

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: Ningbo Shenyu Medical Equipment Co., Ltd.  
Address: No.1318 West of Tanjialing Road, Yuyao  
315408, Zhejiang, China  
SRN: CN-MF-000003330

## Product Information

Name: Manual wheelchairs

### Model:

SYIV100A001	SYIV100A002	SYIV100A003
SYIV100A004	SYIV100A005	SYIV100A006
SYIV100A007	SYIV100A008	SYIV100A009
SYIV100A010	SYIV100A011	SYIV100A012
SYIV100A013	SYIV100A500	SYIV100A501
SYIV100A018	SYIV100A017	SYIV100A016
SYIV100A015	SYIV100A014	SYIV100A502

EMDN: Y122103

Basic UDI-DI: See Annex

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: 2024.12.28

Position: GM

Place: Zhejiang/China



## Annex

Product Name	Model	Basic UDI
manual wheelchairs	SYIV100A001	695057284401JC
manual wheelchairs	SYIV100A002	695057284402JE
manual wheelchairs	SYIV100A003	695057284403JG
manual wheelchairs	SYIV100A004	695057284404JJ
manual wheelchairs	SYIV100A005	695057284405JL
manual wheelchairs	SYIV100A006	695057284406JN
manual wheelchairs	SYIV100A007	695057284407JQ
manual wheelchairs	SYIV100A008	695057284408JS
manual wheelchairs	SYIV100A009	695057284409JU
manual wheelchairs	SYIV100A010	695057284410JD
manual wheelchairs	SYIV100A011	695057284411JF
manual wheelchairs	SYIV100A012	695057284412JH
manual wheelchairs	SYIV100A013	695057284413JK
manual wheelchairs	SYIV100A500	695057284307JK
manual wheelchairs	SYIV100A501	695057284300J5
manual wheelchairs	SYIV100A018	695057284418JV
manual wheelchairs	SYIV100A017	695057284417JT
manual wheelchairs	SYIV100A016	695057284416JR
manual wheelchairs	SYIV100A015	695057284415JP
manual wheelchairs	SYIV100A014	695057284414KM
manual wheelchairs	SYIV100A502	695057284419JX

