



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 14971:2019
EN ISO 15223-1:2021
EN ISO 20417:2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-RX-06.
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:

Address:

SRN:CN-MF-000008761

Product Information

Name: Scoop Stretcher
Model: YDC-4A, YDC-4A02, YDC-4B, YDC-4B02, YDC-4C, YDC-4D, YDC-4E
EMDN: V08050102
Basic UDI-DI: 697444205411JE
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:

Zhou Jianping
Position:GM

