



CERTIFICATE OF CONFORMITY

With European Standards

Name: Suzhou Manwell Medical Equipment Co., Ltd.

Add.: Room B707-A, Tower B, Huijin Business Centre, Yangshe Town, Zhangjiagang City, Jiangsu Province, China

Product Name: Hospital Bed and Accessories

Model or type: See Annex

The submitted sample of the above product has been tested for CE marking according to the following European Directives:

Medical Devices Regulation: 2017/745 / EU MDR

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016

EN ISO 14971:2019+A11:2021

EN ISO 15223-1:2021

EN 1041:2008+A1:2013

EN 60601-1:2006+A2:2021

EN 60601-1-2:2015+A1:2021

The referred report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s).

Regulation 2017/745 / EU on Medical Devices (MDR), ANNEX VIII

The CE marking as shown below can be affixed on the product.

Certificate No.: AV-SZMW20240628052

Date: Jun 28, 2024

for amtre veritas: _____

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Annex to Certificate (No.: AV-SZMW20240628052)

Applicant manufacturer: Suzhou Manwell Medical Equipment Co., Ltd.

Add.: Room B707-A, Tower B, Huijin Business Centre, Yangshe Town, Zhangjiagang City, Jiangsu Province, China

Product Name: Hospital Bed and Accessories

Electric Bed: MA-BE8T、MA-BE5F、MA-BE5T、MA-BE5Z、MA-BE3F、MA-BE3T、MA-BBE01、MA-BN02、MA-EE10、MA-EE11、MA-EE12、MA-EC01、MA-EE13、MA-EE14、MA-EE15、MA-BOE02、MA-HCA、MA-HCB、MA-HCC

Manual Bed: MA-BM1F、MA-BM2F、MA-BM3F、MA-BM3T、MA-BM4F、MA-BM4T、MA-BM00、MA-BME01、MA-BME02、MA-BME03、MA-BME04、MA-BBM02、MA-BOM01、MA-BC02、MA-BC00、MA-BCS02、MA-BC02-A、MA-BN01、MA-BN03、MA-BN04、MA-TB01、MA-TB02、MA-EM01、MA-EM02、MA-EM03、MA-EM04、MA-EM05

Mattress: MA-HM008、MA-HM003、MA-HM004、MA-HM005

Air Mattress: MA-HM006、MA-HM013、MA-HM012、MA-HM015、MA-HM014

I.V. Pole: MA-IV01、MA-IV02、MA-IV03、MA-IV04、MA-IV05、MA-IV06

Bedside Table: MA-HB001、MA-HB002、MA-HB003、MA-HB004、MA-HB005、MA-HB006、MA-HB007、MA-HB008、MA-HB009、MA-HB010

Overbed Table: MA-HOA、MA-HOB、MA-HOC、MA-HOD、MA-HOE、MA-HOF、MA-HOM、MA-HON

Table: MA-CT002、MA-CT002-1、MA-OC014、MA-CT001、MA-CT002、MA-CT003、MA-CT004、MA-CT005

This annex is only valid if attached to the certificate mentioned above

AMTRE VERITAS STANDARD TECHNICAL TESTING LTD.