

EU Declaration of Conformity

Manufacturer: Vistar Medical Supplies Co.,Ltd.
101, 201 &301, No.5 Facility, Datianyang Nansi Rd., Dongfang
Community, Songgang Street, Bao'an District, 518105 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA.
SRN: CN-MF-000011207
European Representative: MedPath GmbH
SRN: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
DE-AR-000000087
Product Name: Reusable Blood Pressure Cuff
Specification: V0111C V0112C V0113C V0114C V0114C-L V0115C V0115C-L V0116C
V0121C V0122C V0123C V0124C V0124C-L V0125C V0125C-L V0126C
V1111C V1112C V1113C V1114C V1114C-L V1115C V1115C-L V1116C
V1121C V1122C V1123C V1124C V1124C-L V1125C V1125C-L V1126C
V0011C V0012C V0013C V0014C V0014C-L V0015C V0015C-L V0016C
V0021C V0022C V0023C V0024C V0024C-L V0025C V0025C-L V0026C
VD-001 VD-002 VD-003 VD-004 VD-005 VA-001(VA-001C) VA-002(VA-
002C) VA-003(VA-003C) VA-004(VA-004C) VA-005(VA-005C) VA-
06(VA-006C) VC-01 VC-02(M5303) VC-SH02 VC-03(M5304) VC-04 VC-
05 VC-06 VF-01 VF-02 VF-03 VF-04 VF-05(M5305) VF-06 VM-AH-1 VM-
AH-2 VM-AH-3 VM-AH-4 VM-AH-5 VM-AH-6 VM-CNT1-5
GMDN Code: 34978
EMDN Code: Z1203020599
BASIC UDI-DI: 697352187RBPCPK
Intended Use: Blood Pressure Cuff is used with blood pressure device like patient
monitor or aneroid sphygmomanometer etc. to measure blood pressure
by, or under the supervision of a licensed physician or other healthcare
provider.

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex
II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare under our sole responsibility that the above-mentioned products meet
the applicable provisions of the Regulation (EU) 2017/745 for medical devices. All supporting
documentation is retained at the premises of the manufacturer.

Applied standards, common specification, guidance: EN ISO 15223-1:2021, EN 1041:2016,
EN ISO 14971:2019, EN 1060-3:1997+A2:2009, EN ISO 81060-1:2012, EN 62366-
1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ASTM D4169-
2022, MDCG 2019-15.

Signature:



Name:

CHEN Zhenxun

Position:

General Manager

Place/date

Shenzhen City, 2025-3-31.

