



Vistar Medical Supplies Co., Ltd.

Declaration of Conformity

Doc #: VS312

Legal Manufacturer: Vistar Medical Supplies Co., Ltd.

Legal Manufacturer's Address: 401, 808-818, Hanhaida Building, No.7 Songgang Avenue, Tantou Community, Songgang Street, Bao'an District, 518105 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

European Authorized Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

We declare under our sole responsibility that:

Blood pressure cuffs & parts

CAN Code: Z1203020599, GMDN Code: 37326&34978

Models: 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 V1011N V1012N V1013N V1014N V1015N V1011C V1012C V1013C V1014C V1014C-L V1015C V1015C-L V1016C V1021N V1022N V1023N V1024N V1025N V1021C V1022C V1023C V1024C V1024C-L V1025C V1025C-L V1026C VD-001 VD-002 VD-003 VD-004 VA-001(VA-001C) VA-002(VA-002C) VA-003(VA-003C) VA-004(VA-004C) VA-005(VA-005C) VA-C-001 VA-C-002 VA-C-003 AH-1 AH-2 AH-3 VC-01 VC-02 VC-03 VC-04 VC-05 VF-01 VF-02 VF-03 VF-04 VF-05 VC-11 VC-12 VC-13 VC-14 VC-15

as described above are in conformity with the requirements as defined in :

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 that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

Vistar Medical Supplies Co., Ltd. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, 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 10993-10:2010, ASTM D4169-2016, MDCG 2019-15.



Vistar Medical Supplies Co., Ltd.

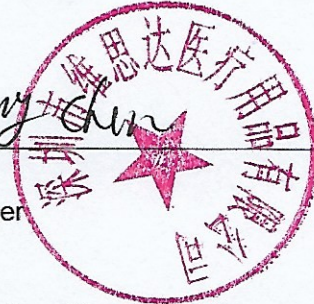
Date:

17th May 2021

Signed:

Chainy Chen

Chainy Chen
General Manager



Vistar Medical Supplies Co., Ltd.

401, 808-818, Hanhaida Building, No.7 Songgang Avenue, Tantou Community, Songgang Street, Bao'an District, 518105 Shenzhen, People's Republic of China

Tel: +86 0755-85298331

Fax: +86 0755-85298409