



Weigao Medical International Co., Ltd.
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PEOPLE'S REPUBLIC OF CHINA

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TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: BJ-CL-087117

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000011328

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.

To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
<2024-05-21>



TÜV SÜD Product Service GmbH
Medical and Health Services

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Mr. Li Xingchun
Conformity Assessment Responsible (CARE)



Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
Device 1 Sterile High Pressure Angiographic Syringes for Single Use 697034977WGGF1022A012AU
Device 2 Sterile Hypodermic Syringes for single use 697034977WGGF1062A010CC
Device 3 Sterile Hypodermic Syringes for Single Use Without Needle 697034977WGGF1011S015E8
Device4 Sterile Infusion Sets for Single Use 697034977WGGF1072B011D2
Device 5 Insulin Pen Needle 697034977ZJKDL062A0024G 697034977ZJKDL062A0164T
Device 6 Syringes for insulin 697034977ZJKDL062A0034J
Device7 Scalp Vein Sets 697034977ZJKDL062A0044L 697034977ZJKDL072B0095J
Device 8 Disposable Needles 697034977ZJKDL062A0054N 697034977ZJKDL072A00757
Device 9 Blood Collecting Needle 697034977ZJKDL062A0064Q 697034977ZJKDL062A0304M
Device 10 Fistula Needle 697034977ZJKDL072B0085G
Device 11 Extension Tube for Single Use 697034977WGGF1021S013EH
Device 12 Sterile Oral/Enteral Syringe for Single Use 697034977WGGF1022A021AV
Device 13 Sterile Transfusion Sets for Single Use 697034977WGGF1072A022CY



Device name or Basic UDI-DI (under MDR application)
Device 14 Plastic blood bags for single use 697034977WGGF1182B023E7
Device 15 I.V.Catheter for single Use 697034977WGJR1072A024QF
Device 16 Tracheal Tubes 697034977GDYK1052A018AX
Device 17 Urethral catheter 697034977GDYK1052A019AZ
Device 18 Silicone Foley Catheters 697034977GDYK1052A020AJ
Device 19 Sterile Heparin Cap for single use 697034977SZHEX041S027LA
Device 20 Stopcock for Single Use (with Extension Tube) 697034977SZHEX022A029FZ
Device 21 Stopcock for Single Use 697034977SZHEX022A031FL