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EU DECLARATION OF CONFORMITY

1. Product name: Disposable Sterile Venous Blood Specimen Collection Needle
2. Trade name: Disposable Sterile Venous Blood Specimen Collection Needle
3. Model and Specification:
 Butterfly Type:27G 3/4",25G 3/4",24G 3/4",23G 3/4",23G 1",22G 3/4",22G 1",21G 3/4",21G 1",20G 3/4" 20G 1"
 Pen type:23G 1",23G 1 1/4",23G1 1/2",22G 1",22G 1 1/4",22G 1 1/2",21G 1",21G 1 1/4",21G 1 1/2", 20G 1",20G 1 1/4" 20G 1 1/2", 18G 1",18G 1 1/4",18G 1 1/2"
 Safety Butterfly Type:27G 3/4",25G 3/4",24G 3/4",23G 3/4",23G 1",22G 3/4",22G 1",21G 3/4",21G 1",20G 3/4" 20G 1"
 Safety Pen type:23G 1",23G 1 1/4",23G 1 1/2",22G 1",22G 1 1/4",22G 1 1/2",21G 1",21G 1 1/4",21G 1 1/2", 20G 1",20G 1 1/4" 20G 1 1/2", 18G 1",18G 1 1/4",18G 1 1/2"
4. Intended use: It is mainly used in combination with disposable vacuum blood collection tube to collect blood samples from human veins.
5. EMDN code: V010402
6. Classification acc. to MDR Ax. VIII: Class IIa , rule 6
7. Conformity assessment procedure: Annex XI, Part A
8. Basic UDI-DI: acc. to GS1

Butterfly Type	697390596JMZ01SS
Pen type	697390596JMZ02SU
Safety Butterfly Type	697390596JMZ03SW
Safety Pen type	697390596JMZ04SY

9. Name and address of the manufacturer or his authorised representative:

Manufacturer:	Shandong Chengwu Medical Products Factory Southern end of Quancheng RoadChengwu County, 274200 Heze City,Shandong Province,PEOPLES REPUBLIC OF CHINA
SRN MF:	CN-MF-000003370
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN EU AR:	DE-AR-000000087

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10. This declaration of conformity is issued under the sole responsibility of the manufacturer:

Shandong Chengwu Medical Products Factory.

11. Object of the declaration (identification of product allowing traceability. It may include a colour image of sufficient clarity to enable the identification of the product, where appropriate.)

12. We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

13. References to the relevant harmonized standards used, or references to the specifications in relation to which conformity is declared:

Regulation/Standard/Guidance	Name of Document
(EU) 2017/745	Medical Device Regulation
EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
MDCG 2021-24	Guidance on classification of medical devices
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices – Guidance on the application of ISO 14971
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
MDCG 2021-5	Guidance on standardization for medical devices
ISO 15223-1:2025	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
ISO 639-1:2002	Codes for the representation of names of languages — Part 1: Alpha-2 code
ISO 22742:2010	Packaging — Linear bar code and two-dimensional symbols for product packaging
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-4:2017	Biological Evaluation of Medical Device - Part 4: Selection of tests for interaction with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-7: 2008 / AC:	Biological evaluation of medical devices - Part 7: Ethylene

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Regulation/Standard/Guidance	Name of Document
2009	oxide sterilization residuals (ISO 10993-7:2008)
EN ISO 10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2009	Biological Evaluation of Medical Devices - Part 11: Tests for systemic toxicity
ISO 9626-2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
ISO 23908-2011	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
ASTM F 1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F88/F88M – 15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886/F1886M–16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 62366-1:2015+A1:2020	Medical devices Part 1: Application of usability engineering to medical devices
IEC TR 62366-2	Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
EN 556-1:2001	Sterilization of medical devices - Requirements for medical

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Regulation/Standard/Guidance	Name of Document
EN 556-1:2001/AC:2006	devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
MEDDEV. 2.7.1 Rev.4	Clinical evaluation: A guide for manufacturers and notified bodies
MEDDEV 2.12/2 Rev2	Post Market Clinical Follow-Up Studies A Guide for Manufacturers and Notified Bodies
MDCG 2020-13	Clinical evaluation assessment report template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies
PD CEN ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers

14. The notified body TÜV SÜD (Notified Body Number 0123): performed Medical Device Regulation (EU) 2017/745, for the placing on the market of Class IIa and Annex VIII Rule 6 and issued the certificate.

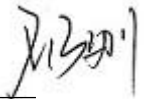
15. Notified Body: TÜV SÜD Product Service GmbH

16. NB Identification Number: 0123

17. CE Certificate No.: G26 103129 0005 Rev.00

18. Valid until: 2031-08-13

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Signature of issue person: 

Name and Position: Naigang Wang Management Representative

Place and Date of issue: Shandong, China, 2026/08/17

