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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-IVDR-099

Product Service

# EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

## No. V11 042464 0039 Rev. 00

**Manufacturer:**

**Zhejiang Gongdong Medical Technology Co., Ltd.**
No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

**SRN Manufacturer:** CN-MF-000005694

**Authorized Representative:**

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V11 042464 0039 Rev. 00

**Report No.:** SH2211102

**Valid from:** 2023-04-11

**Valid until:** 2028-04-10

Marta Carnielli
Head of Notified Body IVD

**Issue date:** 2023-04-11


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# EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

## No. V11 042464 0039 Rev. 00

| | |
|---|---|
| **Classification:** | Class A |
| **Device Group:** | W050101 - BLOOD COLLECTION DEVICES |
| **Intended Purpose:** | IVR 0803 - Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746 |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | - |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2023-04-11 | SH2211102 | Initial issuance |



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