ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-IVDR-099

Digitally signed by Iurchevici Valeriu
Date: 2024.09.04 17:17:15 EEST
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MOLDOVA EUROPEANĂ

TÜV SÜD 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

Issue date: 2023-04-11

Marta Carnielli
Head of Notified Body IVD

"ECHIPAMED-PLUS", SOCIETATEA CU RĂSPUNDERE LIMITATĂ, IDNO 1003600077677, REPUBLICA MOLDOVA, mun. CHIȘINĂU

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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www.zlg.de
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TÜV SÜD
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

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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TÜV®

Zhejiang Gongdong Medical Technology Co.,Ltd.
No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang,
People's Republic of China.
http://www.chinagongdong.com

GONG拱东DONG

Declaration of Conformity

Manufacturer: Zhejiang Gongdong Medical Technology Co.,Ltd.
No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China

European Representative: ZOUSTECHSL.
Pso.Castellana,141-Planta 19,28046-Madrid,Spain

Product Name: Specimen container
Model/Type: with spoon: 20ml,30ml,40ml,60ml,90ml,100ml,120ml;
without spoon: 20ml,30ml,40ml,60ml,80ml,90ml,100ml,120ml;

UMDNS Code: 14303
Classification (IVDD): Others
Conformity Assessment Route: IVDD Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Zhejiang Gongdong Medical Technology Co.,Ltd. is exclusively responsible for the DoC.

DIRECTIVES

General applicable directives:

General applicable directive:
Medical Device Directive: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

StandardApplied:
ISO14971:2019 ISO13485:2016
ISO11135-1:2014 ISO 15223-1:2021

Place, Date of Issue: HuangYan 2021-03-13

Signature:
Name: WeiFeng Zhong
Position: General Manager

ZHEJIANG GONGDONG MEDICAL TECHNOLOGY CO.,LTD 浙江 拱东医疗器械股份有限公司