

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2336910-1

Manufacturer: **Healthwit Medical Technology Co., Ltd.**
19# Innovation Industrial Park, Zibo Economic development Zone, Zibo,
255300 Shandong, P.R. China

EUDAMED Single
Registration No.: CN-MF-000014085

Products: Product of class Is:
The Scope of certification is limited to the aspects relating to Establishing,
Securing, Maintaining Sterile Conditions
T030301 - AIR FLOW BLANKETS
T020401 - STANDARD SURGICAL GOWNS
T020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR
T0205 - NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE
EQUIPMENT - PPE)

Authorised
representative(s): **Riomavix S.L.**
Calle de Almansa 55, 1D, Madrid 28039 Spain.

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2022-08-18

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 190134842 120

Effective date: 2022-08-18

Expiry date: 2027-07-13

Issue date: 2022-08-18



Wenxiang Zhang
TUV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Healthwit Medical Technology Co., Ltd.
19# Innovation Industrial Park, Zibo Economic development Zone, Zibo,
255300 Shandong, P.R. China

Contact

Tel. +49 911 655-5225

Mail: service@de.tuv.com

Date August 18, 2022

Application for: Production Quality Assurance

Certificate No. : HZ 2336910-1

Requirement : MDR 2017/745 Annex IX Chapter I

Dear Madam or Sir,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the certificate No. HZ 2336910-1.

Best regards,

Wenxiang Zhang
Certification body



TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

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Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2336910-1

Organization: Healthwit Medical Technology Co., Ltd.
19# Innovation Industrial Park, Zibo Economic development Zone, Zibo,
255300 Shandong, P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable
Convective Warming Blankets, Disposable Surgical Gowns, Surgical Face
Masks, Disposable Medical Protective Clothings, Isolation Gowns

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190134842 120
Effective date: 2022-08-18
Expiry date: 2025-07-13
Issue date: 2022-08-18



Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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255300 Shandong, P.R. China

Contact

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Mail: service@de.tuv.com

Date August 18, 2022

Application for: QMS

Certificate No. : SX 2336910-1

Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the certificate No. SX 2336910-1.

Best regards,

Wenxiang Zhang
Certification body



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LGA Products GmbH

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