

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 732347 R001

**Manufacturer:** GAUKE Healthcare Co., Ltd

**Address:**

No.8, Jiangbei Highway  
TuanFeng Town  
TuanFeng  
Huang Gang City  
Hubei  
438800  
China

**Single Registration Number:** CN-MF-000013784

**EU Authorised Representative:** MedPath GmbH

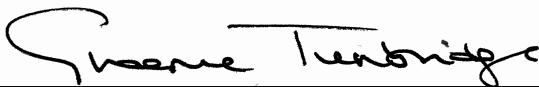
**Address:**

Mies-van-der-Rohe-Strasse 8  
80807 Munich  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-02-22**

Current Issue Date: **2026-02-10**

Starting Validity Date: **2026-02-22**

Expiry Date: **2031-02-21**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Disposable Medical Mask	Class Is
First Aid Dressing Bandage	Class Is
Absorbent Non-Woven Compress	Class Is
First Aid Kit (containing various sizes of First Aid Dressing Bandage & Absorbent Non-Woven Compress)	Class Is
Cotton Tips	Class Is
Bandage	Class Is
Adhesive Bandage	Class Is
Sterile Absorbent Gauze Dressing	Class Is
PVC powder free Medical Examination Gloves	Class Is
Nitrile powder free Medical Examination Gloves	Class Is
Disposable Forceps	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference number	Action
2021-02-22	3255769	Issued.
2021-07-30	3477389	Amended – Change of manufacturer address to No. 82 TuanFeng Avenue. Supplemented – Addition of First Aid Dressing Bandage, Absorbent Non-Woven Compress & First Aid Kit.
2022-03-02	3563833	Supplemented – Addition of Cotton Tips, Bandage, Adhesive Bandage, Sterile Absorbent Gauze Dressing, PVC Medical Examination Gloves, Nitrile Medical Examination Gloves & Disposable Forceps.
2025-05-08	30223707	Amended – Change of manufacturer address to No.8, Jiangbei Highway, TuanFeng Town, TuanFeng, Huang Gang City, Hubei, 438800, China. Amended – Administrative update to previous date formatting, and administrative update to entry ref 3255769 in history.
Current	30569827	Re-Issued – Certificate Renewal. Amended – Scope amended from “PVC Medical examination gloves” and “Nitrile Medical examination gloves” to PVC powder free Medical examination gloves” and “Nitrile powder free Medical examination gloves”.

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