

# EU Quality Management System Certificate

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

## MDR 732347 R000

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

**Address:**

No. 82 TuanFeng Avenue  
TuanFeng Town, TuanFeng  
Huang Gang City  
Hubei  
438800  
China

**Single Registration Number:** Not Available

**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 and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-02-22**

Date: **2021-07-30**

Expiry Date: **2026-02-21**

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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.

# EU Quality Management System Certificate

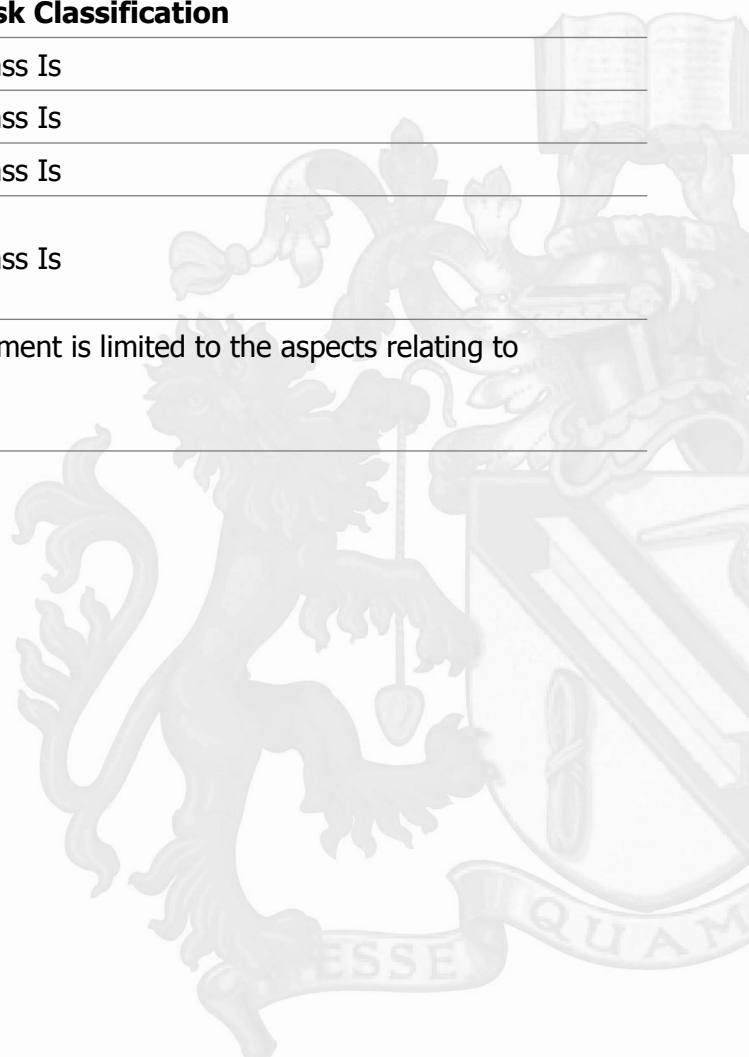
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### Device Schedule: Class IIa, Custom-made and other devices

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

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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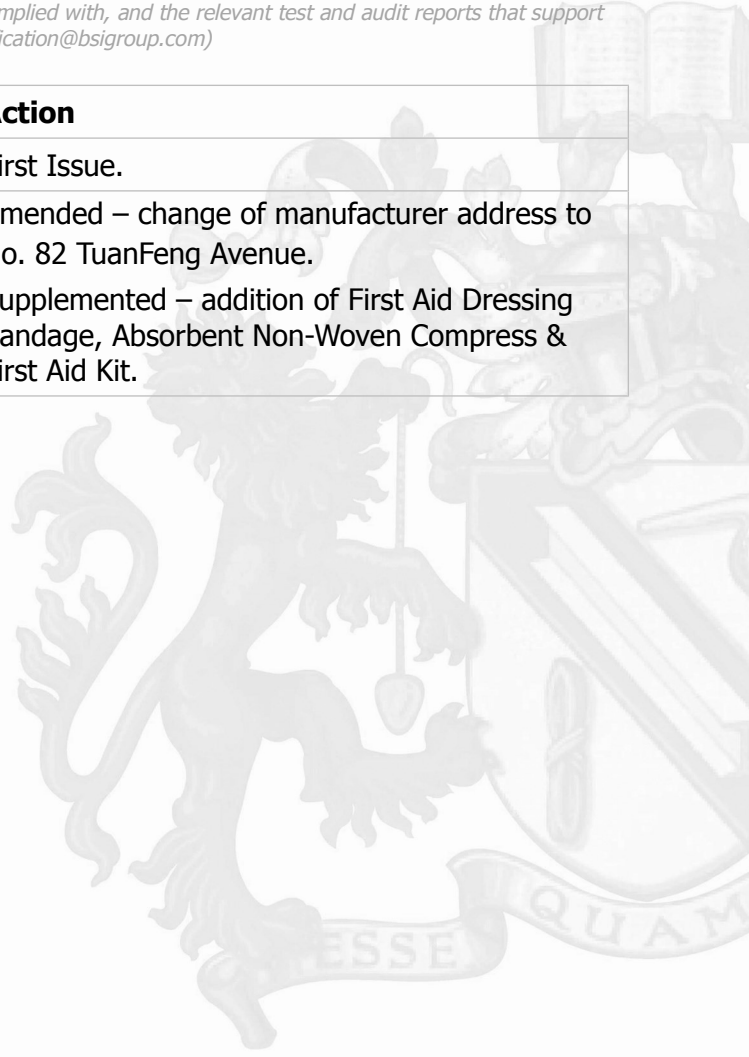
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### Certificate History

*(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)*

Date	Reference number	Action
22 February 2021	3255769	First Issue.
Current	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.



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