

# Documentation Review



No. 5T211118.HHHCD29

**Holder:** Hebei Houde Hanfang Medical Devices Group Co., Ltd.

Beisun Village, Zhengding County, Shijiazhuang City, Hebei Province, China

**Review goal:** Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation 2017/745 Annex I

**Product:** HEALTH PATCH

**Model(s):** *(see the following annex)*

**Classification:** Class I (Not Sterile according to the Manufacturer's declaration - therefore not requiring NB intervention.)

**Review output:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.

Technical documentation identified with the no. TST202111Q2165-1SR dated 2021.11.16

The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

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Expiry date 17 November 2026

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ECM Service Director  
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# Annex I

No. 5T211118.HHHCD29

## Model(s):

3X3CM, 3.5X3.5CM, 3.8X7.5CM, 4.3X16CM, 5X5CM, 5X7CM, 4X11CM, 5X12CM, 5X7.5CM, 5.5X10CM, 5.5X9.5CM, 6.5X9.5CM, 4.5X8.5CM, 6.5X19CM, 6.6X1.9CM, 5.5X1.6CM, 4.5X1.5CM, 7X10CM, 7.5X11CM, 7X9CM, 8X10CM, 7.5X7.5CM, 6X7CM, 7.6X2.9CM, 5X6.7CM, 6X13CM, 7.5X9.5CM, 6.3X12CM, 7.6X11CM, 8X11CM, 8.5X4.5CM, 9.5X5.5CM, 9X9CM, 10X15CM, 11X18CM, 10X10CM, 10X14CM, 10X13CM, 10X12CM, 12X6.5CM, 12.5X11.5CM, 15X35CM, 20X31CM, 20.5X23CM, 6X9CM, 6X7CM, 4X15CM, 4.5X7.5CM, 4.5X15CM, 3.5X7.5CM, 3.5X15CM, 9X3.8CM, 8X3.5CM, 8.5X3.5CM,  $\Phi$ 3CM,  $\Phi$ 6CM,  $\Phi$ 10CM



# CERTIFICATE OF QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate No.016ZB23Q30436R2M  
Unified social credit code:91130100674175886C

This is to Certify that the Quality Management System of

**HEBEI HOUDE HANFANG MEDICAL DEVICES GROUP CO.,LTD**

is in conformity with  
GB/T19001-2016 idt ISO9001:2015 Standard, applies to

PRODUCTION AND SALES OF DRESSINGS AND PATCHES (ONLY LIMITED TO MEDICAL DEVICE PRODUCTION RECORDS AND PRODUCTS LIMITED IN THE LICENSE); GENERAL LIQUID UNIT: SKIN CARE WATER; POWDER UNIT: PRODUCTION AND SALES OF BLOCKY POWDER PRODUCTS (ONLY LIMITED TO PRODUCTS WITHIN THE SCOPE OF COSMETICS FILING); PRODUCTION AND SALES OF HEALTH CARE STICKERS AND DAILY NECESSITIES (POWDER, FEVER, GEL, HOT-MELT ADHESIVE, DRESSING, CATAPLASM, LIQUID AND PATCH) (EXCEPT THOSE REQUIRING SPECIAL APPROVAL) (NO BRANCH IS INCLUDED IN THE SCOPE OF THIS CERTIFICATE SYSTEM)

REGISTERED ADDRESS:BEISUN VILLAGE, ZHENGDING COUNTY, SHIJIAZHUANG, HEBEI PROVINCE, P.R.C.

OPERATION ADDRESS:ROOM 1603, BUILDING A, JINHE INTERNATIONAL BUSINESS, ZHENGDING COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINCE; NO. 1 ZHENGXING ROAD, BEISUN INDUSTRIAL ZONE, ZHENGDING COUNTY, SHIJIAZHUANG CITY, HEBEI PROVINCE (PRODUCTION ADDRESS)

Date of Initial Issuance:Mar. 13, 2017  
Date of Re-certification Issuance:Mar. 8, 2023  
Date of Expiration:Mar. 12, 2026

BCC Inc.  
President:



BCC Address: Room 1101, Floor 11, Building 1, Guoyingyuan, Xicheng District, Beijing, P.R.C.  
This certificate is valid within state - specified validities of administrative and qualification licensing.  
The effectiveness of this certificate shall be maintained by regular surveillance audit,  
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MANAGEMENT SYSTEM  
CNAS C016-M



# CERTIFICATE OF FDA REGISTRATION SERVICE



HEREBY CERTIFY THAT  
**HEBEI HOUDE HANFANG MEDICAL DEVICES  
GROUP CO.,LTD**

FDA US AGENT

IRC USA  
[www.IRC-US.com](http://www.IRC-US.com)

HAS SUCCESSFULLY COMPLETED/UPDATED  
THE FDA REGISTRATION

FOR

OWNER/OPERATOR NUMBER: 10033948  
ESTABLISHMENT REGISTRATION NUMBER: 3008693666  
MEDICAL DEVICE LISTING NUMBER (MDL/LST):

MDL	Product Code	510K	Class	GMP/UDI	Device Name
D107316	KGX	Exempt	1	Yes	FOOT PATCH; FOOT MASK;SLIMMING PATCH; HEALTH PATCH
D151082	FRL	Exempt	1	No	ABSORBENT PAD/ADHESIVES
D226676	IMD	Exempt	1	Yes	HOT COLD DISPOSABLE PACK
D479362	MDA	Exempt	1	Yes	SILICONE SHEET

*Charlie Mack*

PRINCIPAL ENGINEER

CERTIFICATE NO.:IRC-HD-202208



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