

EU Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL

Doc. No.: CE-MDR-BK-04-DOC-01

Manufacturer: Wuhan Pakcare Bio-Technology Co., Ltd.
No. 28-1, Linkong North Road, Hengdian Street,
Address: Huangpi district, Wuhan city, 430301 Hubei, P.R.
China

**Single Registration
Number (SRN) of the** CN-MF-000008960

Manufacturer:
Authorised representative Share Info GmbH
(AR):

Address: Heerdter Lohweg 83, 40549 Düsseldorf

**Single Registration
Number (SRN) of AR:** DE-AR-000005132

We, the manufacturer, declare under our sole responsibility that:

the medical device(S)	Product Name:	Hot Cold Pack
	Type/model,	M700B1, M600B1, B000B0-1, G03245, G03246,
	identification of product allowing traceability (Where applicable):	G03247, G03249, G03251, G03252, G03254, VM- CM1, VM-CM2, VM-CM3, VM-CM4, VM-CM5, VM- CM6, GBDF1, CMDF1, B031B2, M513C0, M514B0C, M515B0C, B000B1, B012B1, B020B1, B031B1, B053B1, B060B1, M002B1, M500B1, B012B2, M520B2, B055B2, E010B0, E020B0, E040B2, E030B1, E100B1with elastic band, E080LOG, E010C1, E040C2, E030C1, E100C1, E080C1, ZN11W4S0-1, E991K8-2, E991K8-3, E991K8-4, E180K14, E18K13C, E040K13-1, EM0201, E040B2G, EO0022-2, ZN4W2W12S01-2, E030L1, E100L1, E110B2, E19CN0, E090L0, E310L0, E040B2-1, E031L0G, E101L0G, E041L1G, E011L0G, E021L0G, E010L0G, E020L0G, E090L0G, E081L0G, B013B0, E013L0G, E016L0G, E000B0, E09CN0, E100C1M, M402I19, M403I19, E30L14C, ZN6W1W2S0, E110B0, E040B2A, EM0202, C919BOC items, C901LO items, C502B0, B072B1, B009B0C, M715K8-3, M716K8-4, M715K8-4, M716K8-5, M718F11, ZN2W2S2, ZN4W2SD-1, ZN1W7W13, M010L8, C901LO-1, B011G0C, B072B1-1, ZN1W1S0, G03253, C919B1, M010L9, M003L15, L009L0, C060B0, C061B0,



C925B0, C926B0, C927B0, C919B0, C920B0,
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C042B0, C043B0, C044B0, C045B0, C118B0,
C119B0, C901M0, B011G8, M017K-1, M017K-2,
M017K-3, E112B1, M421R13K-1, M421R13K-2,
E20B11K, M420B11K, EM0203, E040KF16C,
M720B13T-1, M720B13T-2, M720B13T-3, M720B13T-
4, M720B13T-5, M720B13T-6, M720F13T-1,
M720F13T-2, M720F13T-3, M720F13T-4, M720F13T-
5, M720F13T-6, M538L11K-2, M538L11K-4,
M538L11K-3, M538L11K-6, M538L11K-1, M538L11K-
5, M700K8, B009C0C, B074B0C, B092B0C,
ZN1W13W14S5, ZN1W4S1-1, ZN1W4S1-2,
ZN1W4S1-3, ZN1W4S1-4, ZN1W7W17SD-1, E32L0F,
C901L8F, M538L141C, M541K141K, B073L14,
B093L14, B02L1G, B015L7, M512L4, M513L4,
M515L4, M510L4, M005L4, B015L4, M012L9,
M013L9, B120L8, B200L8, ZN11W4S8, B210L0C-00,
ZN1W2S9, ZN1W2S15, ZN1W12S8-1,
ZN1W11W14S5, B151S11, E180S11, E040S11,
ZN1W7S4, ZN1W7S5, 007923, 007817, 007978,
007985, 007930, W007, M511L4, UP4405, B210L0C-
02, ZN1W7W16S1, M514L4, M013L9-2, M013L9-3,
M004CN0C(2350058), M003CN0C(2350057),
M500CN0C(2350056), ZN1W4S4, ZN1WAS9,
ZN1WAS9-1, ZN1W4SD, Assortment E, ZNP-001,
Assortment 2, ZN1W3W7S7-1, ZN1W2S9-2,
ZN1W2S9-3, ZN4W4S5-1, ZN4W4S5-2, E040K13-2,
ZN4W4S4-P, ZN3W2S2-2P, 007855, 007862, 007879,
007756, 007763, 007725, 007718, ZN1W1SD-1,
ZN1W1SD-2, M013M0, M517M0, ZN1W3S0,
B171S11, M900M11, CM6711L7C, CM6712L7,
M400L18C, M002CN1, M500CN1, M509CN2,
M510CN2, M520CN2, M010CN16C, M420K13,
M800K13, E041KF24, M101S24P-1, M101S24P-2,
B072KF24, M601KF24, M551KF24, B170L1, B010L1,
ZN1W3W7S3-XL, ZN1W3W7S9, ZN1W3W7S7,
ZN1W3W7S6, B210L0C-01, ZN1W2S1-1, ZN1W2S1,
ZN1W5W7S9-1, ZN1W3W7S3S4, ZN1W14W17S4,
ZN1W7W13S5-4, M401L19C, B180L0C-2,
WZNIW14S9, B161L4C-1A, WZNIW17S7,
WZNIW14S5, B032L4C-1, B019L4C-1, B054L4C-1,
B055L4C-1, B161L4C-1, B160L4C-1, B021L4C-1,
B003L4C1-1, B180L0C-1, WZNIW7S7-3,

WZN1W7S6, WZN1W4S1, E040K13C, B15K12C,
M520K12C, B080K12C, B140K12C, M540F11,
M550F11, M600F11, B151F11, E040F11, E180F11,
M520F11C, M520F11, M520F11H, ZN4W2W12S01,
ZN4W2S5-1, ZN4W2S9-1, ZN4W2W12S03,
ZN4W15S0, E180F15, M011F15-1, M011C11-1,
ZN3W3S2, ZN4W2S9-2, ZN4W2W12S01-1, E180F-
15, E040F11C-P, ZN4W4S5
M011F11-1, M011F11-2, M011F11-3, M012F13C-1,
M012F13C-2, M541F141, E18F13C, M410F17C,
M101F13-2, M101F13-1, E10F11P, M420F11P,
M012W25C, ZN1W5S8, ZN1W5S5, ZN1W5S3,
ZN1W5S9, ZN1W5S5-1, ZN1W5S1, ZN1W5S7,
ZN1W5S5-2, ZN1W5S9-2, ZN1W5W7S9, ZN1W5S9-
3, ZN1W2SD, ZN1W2SD-1, ZN1W2S2, ZN1W2S2-1,
ZN1W2S2-2, ZN1W8SD, ZN1W14S0, ZN1W14S4,
ZN1W14S5, ZN1W14SD, ZN1W14S9, ZN1W14S7,
ZN1W37S23, ZN1W14S5-2, WN1W7S3, WN1W7S9,
WN1W7S5, WN1W7S7, WN1W7S4, WB012, WB013,
WB016, WB014, WB015, WB017, WB018, WB011,
WB020, WB009, WB019, WB022, WB021,
M520IC18H, M540IC18, M550IC18, M600IC18,
M021IC18, M022IC18, B000L8, E041L7, B010L8,
M520L8, B030L8, B050L8, M009L8, M003L8,
ZN1W7S9-3, 02401, 02402, C053B0, C036B0,
C007B0, C010B0, C006B0, 657001, 657002,
M011S1, 5684, 5685, 5686, WB025, ZN4W2SD-1,
ZN4W2SD-2, ZN4W2SD-4, ZN4W2SD-5, ZN4W2SD-
6, ZN4W2SD-7, ZN4W2SD-8, M718F11-2, M718F11-
3, M718F11-4, M718F11-5, M719F11-1, M719F11-2,
M719F11-3, M719F11-4, B011G0C-pink, 671001,
671002, 736006, 736007, M5210B0C, M900M12,
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5661, 5660, 5659, W-ZN2W14M1, ZN4W2W12S06,
PT03, PT04, PT01, PT02, LE-002, 0001, 0002,
061511, ZN1W12S1-2, W010, W011, B180L0C-1-1,
WZN1W7S4, B163L4C-1, WZN1W7S4-2,
WZN1W14S8, 694001, M002B1-1, E102CN1,
E022CN1, M030CN1, M602CN1, E010B0-1,
15214500, 15214520, 15214510, E100C2, E030B1-2,
MY-103, LAS010621, E071B0, E040L7, ZN1W7S9-5,
ZN1W7S9-3, ZN1W4S8, ZN1W714S9, NSFYZ,
NSFTD, Riixo-007, YMZUXZ, YMZDGN1, YMZDGN2,
YMZHH1, YMZHX, YMZHY, YMZJZ, YMZMZ,

	YMZNST, YMZNX1, YMZNX2, YMZRSD, YMZRD, YMZTD, YMZHJ, YMAXBZ, YMZNX1-B, YMZNX1-A, ZN3N4W2S2, B017K8-4, M540F11-1, M540F11-2, ZN4W2W12S02, M420F13, 48x12-XL Blue, 48x12-XL Gray, 68x12-XLL Blue, 68x12-XLL Gray, M550F11P, YDSYZ, NDSYZ, NDSYZB, E040WS19, M010WS141, M029WS141, M520WS41, M508WS141, M5401F141, RT002, M538L142C-1, NJBWJ, WB009S, WB009M, WB010, WB010B, WB025, WB023, WB024, NJMZT, LMBHYA, LVBHW, LMBHY, LMBHT, LMBHX, LMBHHB, LMBHHJ, M512C4, M513C4, M515C4, M510C4, M005C4, B015C4, M012C9, M013C9, M512C4-1, LMBHT, EM0203L, E040L16C
EMDN Code:	M9001
Intended Purpose:	The Hot Cold Pack is a medical device used to help relieve fevers, bruises, swelling, muscle spasms, aches and pains, headaches, first-degree burns and fatigue.
Classification: (Annex VIII of the MDR)	Class I according to Rule 1
Basic UDI-DI:	697358909HP100MD
Conformity assessment procedure:	EC Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post Market Surveillance (Annex III)
Applied harmonized standards and Common Specification:	<i>Refer to the Appendix I for details.</i>
Notified Body:	--
Address:	--
Notified Body number:	--
Certificate(s) number.:	--
Expire date of the Certificate:	--
Start of CE Marking:	--

The product concerned has been manufactured under a quality management system according to Annex IX of Regulation (EU) 2017/745.

The above-mentioned declaration of conformity was prepared by following the Annex IV of Regulation (EU) 2017/745 and is exclusively under the responsibility of the

manufacturer.

Wuhan Pakcare Bio-Technology Co., Ltd.

No. 28-1, Linkong North Road, Hengdian Street, Huangpi district, Wuhan city, 430301
Hubei, P.R. China



Appendix I: Applied harmonized standards and Common Specification

is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Applied harmonized standards and Common Specification

Regulation (EU) 2017/745:	EN ISO 10993-1:2020
2017+A1:2020	
MEDDEV 2.7.1 rev.4:2016	EN ISO 10993-5:2009
MEDDEV 2.12.1 rev.8:2013	EN ISO 10993-10:2023
EN ISO 13485:2016/A11:2021	EN ISO 10993-23:2021
EN ISO 14971: 2019/A11:2021	EN ISO 15223-1:2021
EN ISO/TR 24971: 2020	EN ISO 20417:2021

This DoC is valid from 2023.08.21.

Authorized by:



Signature (on behalf of the manufacturer)

Position: General Manager

Rev.: 1.0

Signed on: 2023.08.21.

Place: Hubei, China