No. SCC(18)-5080A-RoHS

CHINA CEPREI (SICHUAN) LABORATORY
No.45 Wen Ming Dong Road
Longquanyi Chengdu Sichuan P.R. China

RoHS DECLARATION OF CONFORMITY

RoHS DECLARATION OF CONFORMITY is hereby responsibility of the Name Grantee/ Responsible Party and issued to certify the following equipment:

Test requested:
1) To determine the Cadmium Content of the submitted sample.
2) To determine the Lead Content of the submitted sample.
3) To determine Mercury Content of the submitted sample
4) To determine Hexavalent Chromium Content of the submitted sample
5) To determine Polybrominated Diphenyl Content of the submitted sample
6) To determine Polybrominated Diphenyl Ehers Content of the submitted sample

Client	Yongkang Kapu Houseware Co., Ltd.
Address	Xialiao Village, Shizhu Town, Yongkang City, Zhejiang Province, China
Manufacturer	Yongkang Kapu Houseware Co., Ltd.
Address	Xialiao Village, Shizhu Town, Yongkang City, Zhejiang Province, China
Sample	Portable Water Filter
Model	K8625, K8612, K8612S, K8612A, K8618, K8621, K8630
Date of issue	Oct. 10, 2018

The submitted sample of the above equipment has been tested for CE marking to RoHS European Directive (2011/65/EU – Restriction of the use of hazardous substance) and following standards.

Test standards	EN 62321:2009 EN 50581:2012

This DOC is only valid in connection with the test report below:

Report number	SCC(18)-50010A-5-10-RoHS

Test Report No.: 721673981
Report Date: 17 August 2022

SUBJECT	**Chemical Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Yongkang Kapu Houseware Co.,Ltd.**
CLIENT ADDRESS	NO.88 Xialiao Industrial Park Shizhu Town Yongkang City, China
TEST PERIOD	08-Aug-2022~16-Aug-2022
RESULT SUMMARY	The tested items **complied with** German Food & Feed Acts of September 1, 2005 (LFGB), Section 30 and 31, BFR Recommendations VI and III; European COMMISSION REGULATION (EU) No 2020/1245, (EU) No 10/2011 and its amendments - Overall migration test **001~002 PASS** - Specific Migration of Heavy metal **001~002 PASS** - Color release **001~002 PASS** - Peroxide Value **001~002 PASS** - Volatile Organic Compounds **001~002 PASS**

Prepared By

Wei Jun

(Wei Jun)
Report Drafter

Authorized By

Leo liu

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuvsud.com
Webpage: www.tuvsud.com

Regional Head Office:
TUV SUD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

RECEIPT DATE / TEST DATE

08-Aug-2022/ 08-Aug-2022

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Water filter straw
Sample Specification: K8612,K8612M,K8612S,K8612A,K8625
Batch No./Date: 20220801
Manufacturer: /

SAMPLE NO.	TEST PART	DESCRIPTION	PHOTOGRAPH
721673981-1	001	Blue plastic	
721673981-2	002	Blue plastic	

TEST RESULT(S)

Note: The migration results in this report were tested and expressed based on repeated use articles.

1. Overall Migration Test
   - Test method: With reference to EN 1186-3:200
   - Sample 001~002 Migration ratio(S/V): 10dm²/L

Simulant (s) Used	Test Condition	Result(s) [mg/dm²]			Maximum Permissible Limit [mg/dm²]
		001			
		1st migration	2nd migration	3rd migration	
Distilled Water	70°C for 2 hours	<3.0	<3.0	<3.0	10
Stability: Comply					

Simulant (s) Used	Test Condition	Result(s) [mg/dm²]			Maximum Permissible Limit [mg/dm²]
		002			
		1st migration	2nd migration	3rd migration	
Distilled Water	70°C for 2 hours	<3.0	<3.0	<3.0	10
Stability: Comply					

2. Specific migration of Heavy metals
   - Test method: With reference to EN13130-1:2004, followed by ICP-MS.
   - Test condition: Distilled Water, 40°C for 2 hours
   - Sample 001~002 Migration ratio(S/V): 6dm²/L

Test Item(s)	Result(s) [mg/kg]			Maximum Permissible Limit [mg/kg]
	001			
	1st migration	2nd migration	3rd migration	
Lithium (Li)	<0.1	<0.1	<0.1	0.6
Aluminium (Al)	<0.1	<0.1	<0.1	1
Chromium (Cr)	ND	ND	ND	ND (DL:0.01)
Manganese (Mn)	<0.1	<0.1	<0.1	0.6
Iron (Fe)	<5	<5	<5	48
Cobalt (Co)	<0.01	<0.01	<0.01	0.05
Nickel (Ni)	<0.01	<0.01	<0.01	0.02
Copper (Cu)	<1	<1	<1	5
Zinc (Zn)	<1	<1	<1	5
Arsenic (As)	ND	ND	ND	ND (DL:0.01)
Cadmium (Cd)	ND	ND	ND	ND (DL:0.002)
Antimony (Sb)	<0.01	<0.01	<0.01	0.04
Barium (Ba)	<0.1	<0.1	<0.1	1
Mercury (Hg)	ND	ND	ND	ND (DL:0.01)
Lead (Pb)	ND	ND	ND	ND (DL:0.01)
Lanthanum (La)	<0.01	<0.01	<0.01	0.05
Europium (Eu)	<0.01	<0.01	<0.01	0.05
Gadolinium (Gd)	<0.01	<0.01	<0.01	0.05
Terbium (Tb)	<0.01	<0.01	<0.01	0.05
Sum of [La, Eu, Gd, Tb]	<0.04	<0.04	<0.04	0.05
Stability: Comply				

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuvsud.com
Webpage: www.tuvsud.com

Regional Head Office:
TUV SUD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Item(s)	Result(s) [mg/kg]			Maximum Permissible Limit [mg/kg]
	002			
	1st migration	2nd migration	3rd migration	
Lithium (Li)	<0.1	<0.1	<0.1	0.6
Aluminium (Al)	<0.1	<0.1	<0.1	1
Chromium (Cr)	ND	ND	ND	ND (DL:0.01)
Manganese (Mn)	<0.1	<0.1	<0.1	0.6
Iron (Fe)	<5	<5	<5	48
Cobalt (Co)	<0.01	<0.01	<0.01	0.05
Nickel (Ni)	<0.01	<0.01	<0.01	0.02
Copper (Cu)	<1	<1	<1	5
Zinc (Zn)	<1	<1	<1	5
Arsenic (As)	ND	ND	ND	ND (DL:0.01)
Cadmium (Cd)	ND	ND	ND	ND (DL:0.002)
Antimony (Sb)	<0.01	<0.01	<0.01	0.04
Barium (Ba)	<0.1	<0.1	<0.1	1
Mercury (Hg)	ND	ND	ND	ND (DL:0.01)
Lead (Pb)	ND	ND	ND	ND (DL:0.01)
Lanthanum (La)	<0.01	<0.01	<0.01	0.05
Europium (Eu)	<0.01	<0.01	<0.01	0.05
Gadolinium (Gd)	<0.01	<0.01	<0.01	0.05
Terbium (Tb)	<0.01	<0.01	<0.01	0.05
Sum of [La, Eu, Gd, Tb]	<0.04	<0.04	<0.04	0.05
Stability: Comply				

Note: 1. DL denotes Detection Limit
2. ND denotes Not Detected and less than Detection Limit.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuvsud.com
Webpage: www.tuvsud.com

Regional Head Office:
TUV SUD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

3. Color release
   - Test method: With reference to Kunststoffe im Lebensmittelverkehr Book II, Teil B II, IX

Simulant(s) Used	Test Condition	Result(s)		Permissible Limit
		001	002	
Water	50ºC for 5 hours	No bleeding	No bleeding	No bleeding

Note: 1. No bleeding denotes no difference was found between blank and sample
2. Bleeding denotes staining was found from sample

4. Peroxide Value
   - Test method: With reference to Bundesgesundheitsbl. 40 (1997), 412.

Test Item(s)	Result(s)		Maximum Permissible Limit
	001	002	
Peroxide Value	Absent	Absent	Absent

5. Volatile Organic Compounds
   - Test method: With reference to Bundesgesundheitsblatt 25 (1982) 334.
   - Test condition: 90°C for 24 hours

Test Item(s)	Result(s) [mg/dm^2]	Maximum Permissible Limit [mg/dm^2]
	001	
Volatile Organic Components	2.3	15

Note: The samples pictured below have been confirmed by the customer to be of the same material as the sample tested.

Whole product:

Note: This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuvsud.com
Webpage: www.tuvsud.com

Regional Head Office:
TUV SUD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report No.: 721625277
Report Date: 26 April 2016

ORIGINAL

SUBJECT	**Chemical Test**
TEST LOCATION	**TÜV SÜD China**
	TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**YONGKANG KAPU HOUSEWARE CO.,LTD**
CLIENT ADDRESS	Xiaoliao Village, Shizhu Town, Yongkang City, Zhejiang Province, China
TEST PERIOD	18-Apr-2016~22-Apr-2016
TEST REQUEST	1. In accordance with US FDA 21 CFR 177.1520 2. In accordance with US FDA 21 CFR 180.22 & 181.32.
CONCLUSION	**PASS** 1. The submitted sample with test part(s) 001 was found to **comply with** the requirement(s) as specified in FDA 21 CFR 177.1520 for olefin copolymers used in contact with food for the food simulation solvent used. 2. The submitted sample with test part(s) 002~003 were found to **comply with** the requirement of acrylonitrile monomer content for finished food-contact articles containing acrylonitrile copolymers and resins as specified in FDA 21 CFR 180.22 & 181.32.

Prepared By

(Cynthia Cao)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda. (5)The test result can be used by client for quality control.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4,No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

ORIGINAL

RECEIPT DATE/ TEST DATE

18-Apr-2016/ 18-Apr-2016

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Water Filter Straw
Sample Specification: K8612
Batch No./Date: /
Manufacturer: YONGKANG KAPU HOUSEWARE CO.,LTD

SAMPLE NO.	TEST PART	DESCRIPTION	PHOTOGRAPH
721625277-1	001	Dark blue plastic	
721625277-2	002	Light blue plastic	
721625277-3	003	Dark blue plastic	

TEST METHOD(S)

1. Test for compliance with FDA 21 CFR 177.1520
   - With reference to FDA 21 CFR 177.1520

2. Test for compliance with FDA 21 CFR 180.22 & 181.32
   - With reference to FDA 21 CFR 180.22 & 181.32

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4,No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

ORIGINAL

TEST RESULT(S)

1. Test for compliance with US FDA CFR 21 Part 177.1520

Test Item	Result	FDA Specification
	001	
Density at 23°C (g/cc)	0.920	0.85-1.00
n-Hexane extractives at 50°C , w/w (%)	0.5	5.5
Xylene extractives (%) at 25°C, w/w (%)	2.2	11.3

Note:
1. g/cc denotes gram per cubic centimeter
2. °C denotes degree Celsius
3. % denotes percentage by weight
4. Specification is quoted from FDA 21 CFR 177.1520

2. Test for compliance with US FDA CFR 21 Part 181.32

Test Conditions	Acrylonitrile monomer content [mg/inch^2]		FDA Specification [mg/inch^2]
	002	003	
Distilled Water at 120°F for 24 hours	<0.001	<0.001	0.003

Note:
1. °F denotes degree Fahrenheit
2. mg/in^2 denotes milligram per squre inch
3. < denotes less than
4. Specification is quoted from US FDA CFR 21 Part 180.22 & 181.32

Notice: The samples pictured below have been confirmed by the customer to be of the same material as the sample tested and as such they can be expected to have the same test result.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4,No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report No.: 721625277
Report Date: 26 April 2016

ORIGINAL

SUBJECT	**Chemical Test**
TEST LOCATION	**TÜV SÜD China**
	TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**YONGKANG KAPU HOUSEWARE CO.,LTD**
CLIENT ADDRESS	Xiaoliao Village, Shizhu Town, Yongkang City, Zhejiang Province, China
TEST PERIOD	18-Apr-2016~22-Apr-2016
TEST REQUEST	1. In accordance with US FDA 21 CFR 177.1520 2. In accordance with US FDA 21 CFR 180.22 & 181.32.
CONCLUSION	**PASS** 1. The submitted sample with test part(s) 001 was found to **comply with** the requirement(s) as specified in FDA 21 CFR 177.1520 for olefin copolymers used in contact with food for the food simulation solvent used. 2. The submitted sample with test part(s) 002~003 were found to **comply with** the requirement of acrylonitrile monomer content for finished food-contact articles containing acrylonitrile copolymers and resins as specified in FDA 21 CFR 180.22 & 181.32.

Prepared By

(Cynthia Cao)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda. (5)The test result can be used by client for quality control.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4,No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

ORIGINAL

RECEIPT DATE/ TEST DATE

18-Apr-2016/ 18-Apr-2016

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Water Filter Straw
Sample Specification: K8612
Batch No./Date: /
Manufacturer: YONGKANG KAPU HOUSEWARE CO.,LTD

SAMPLE NO.	TEST PART	DESCRIPTION	PHOTOGRAPH
721625277-1	001	Dark blue plastic	
721625277-2	002	Light blue plastic	
721625277-3	003	Dark blue plastic	

TEST METHOD(S)

1. Test for compliance with FDA 21 CFR 177.1520
   - With reference to FDA 21 CFR 177.1520

2. Test for compliance with FDA 21 CFR 180.22 & 181.32
   - With reference to FDA 21 CFR 180.22 & 181.32

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4,No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

ORIGINAL

TEST RESULT(S)

1. Test for compliance with US FDA CFR 21 Part 177.1520

Test Item	Result	FDA Specification
	001	
Density at 23°C (g/cc)	0.920	0.85-1.00
n-Hexane extractives at 50°C , w/w (%)	0.5	5.5
Xylene extractives (%) at 25°C, w/w (%)	2.2	11.3

Note:
1. g/cc denotes gram per cubic centimeter
2. °C denotes degree Celsius
3. % denotes percentage by weight
4. Specification is quoted from FDA 21 CFR 177.1520

2. Test for compliance with US FDA CFR 21 Part 181.32

Test Conditions	Acrylonitrile monomer content [mg/inch^2]		FDA Specification [mg/inch^2]
	002	003	
Distilled Water at 120°F for 24 hours	<0.001	<0.001	0.003

Note:
1. °F denotes degree Fahrenheit
2. mg/in^2 denotes milligram per squre inch
3. < denotes less than
4. Specification is quoted from US FDA CFR 21 Part 180.22 & 181.32

Notice: The samples pictured below have been confirmed by the customer to be of the same material as the sample tested and as such they can be expected to have the same test result.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4,No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

No. SCC(18)-5080A-RoHS

CHINA CEPREI (SICHUAN) LABORATORY
No.45 Wen Ming Dong Road
Longquanyi Chengdu Sichuan P.R. China

RoHS DECLARATION OF CONFORMITY

RoHS DECLARATION OF CONFORMITY is hereby responsibility of the Name Grantee/ Responsible Party and issued to certify the following equipment:

Test requested:
1) To determine the Cadmium Content of the submitted sample.
2) To determine the Lead Content of the submitted sample.
3) To determine Mercury Content of the submitted sample
4) To determine Hexavalent Chromium Content of the submitted sample
5) To determine Polybrominated Diphenyl Content of the submitted sample
6) To determine Polybrominated Diphenyl Ehers Content of the submitted sample

Client	Yongkang Kapu Houseware Co., Ltd.
Address	Xialiao Village, Shizhu Town, Yongkang City, Zhejiang Province, China
Manufacturer	Yongkang Kapu Houseware Co., Ltd.
Address	Xialiao Village, Shizhu Town, Yongkang City, Zhejiang Province, China
Sample	Portable Water Filter
Model	K8625, K8612, K8612S, K8612A, K8618, K8621, K8630
Date of issue	Oct. 10, 2018

The submitted sample of the above equipment has been tested for CE marking to RoHS European Directive (2011/65/EU – Restriction of the use of hazardous substance) and following standards.

Test standards	EN 62321:2009 EN 50581:2012

This DOC is only valid in connection with the test report below:

Report number	SCC(18)-50010A-5-10-RoHS

FDA

Fiscal Year 2025

This is a notice to the establishment whose Facility Registration and Device Listing have been done within the Fiscal Year 2025.

Establishment information

Name: NINGBO GUANGBO MEDICAL TECHNOLOGY CO.,LTD

Address: NO.668-1 Nanmiao cillage, Lizhou street, Yuyao, Ningbo, Zhejiang, 315400, CHINA

Inquiry Website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Facility Registration and Device Listing Information

Owner/Operator Number: 10081109			
Registration Number: 3015069920			
Listing No.	**Product Code**	**Proper Name(s)**	**Registration Role**
D439786	OEA	Non-surgical isolation gown	Manufacturer
D439787	LYU	Accessory, Surgical Apparel (Face mask)	
D439788	FRL	Gauze Pad	
D439789	OHO	First Aid kit	
D439790	NAC	Adhesive bandage	
D439791	GAX	Silicone tourniquet	
D497242	NAB	Non-Woven Gauze Swab	
D497243	LRW	Scissors	
D497244	ILI	Triangular Bandage	
D497245	KME	Emergency Blanket	
D497246	KYR	Ice Pack	
D497247	IMA	Hot Pack	
D497248	LRJ	Alcohol Prep Pad, BZK Prep Pad, Hydrogen Peroxide Prep Pad, Pofidone-Lodine Prep Pad, Eye Wash, Hand sanitizer, Waterless Hand Sanitizer	
D497249	JSG	Saline Solution	
D497250	MHW	Wound/Burn Dressing	
D497251	NAE	Burncare relieve burn gel	
D497252	FQM	Elastic Bandage, Cotton Gauze Bandage	

Reg

D497253	EFN	Cotton Stick, Cotton Stick	
D497254	HTD	Forceps	
D521434	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydriatic eyewear)	

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00345996

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA61**		
	Bezeichnung / Name **Regierung von Oberbayern**		
	Staat / State **Deutschland**		Land / Federal state **Bayern**
	Ort / City **München**		Postleitzahl / Postal code **80534**
	Straße, Haus-Nr. / Street, house no. **Maximilianstraße 39**		
	Telefon / Phone **+49-89-21760**		Telefax / Fax **+49-89-21762914**
	E-Mail / E-mail **medizinprodukteanzeigeverfahren@reg-ob.bayern.de**		

Anzeige / Notification

	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **13.07.2021**		Registriernummer / Registration number **DE/CA61/00179085**

Rechtsgrundlage / legal basis

☐ Medizinprodukte (93/42/EWG bzw. 90/385/EWG) / German Medical Device Act (93/42/EWG or 90/385/EWG)

☒ Verordnung (EU) 2017/745 (MDR) / Regulation (EU) 2017/745 (MDR)

Typ der Anzeige / Notification type

☒ Erstanzeige / Initial notification

☐ Änderungsanzeige / Notification of change

☐ Widerrufsanzeige / Notification of withdrawal

Frühere Registriernummer bei Änderungs- und Widerrufsanzeige
Previous registration number if notification has been changed or withdrawn

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG

☐ Hersteller / Manufacturer

☒ Bevollmächtigter / Authorised Representative

☐ Einführer / Importer

☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG / Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG

☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV
Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV

☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG
Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG

Anzeigender / Reporting organisation (person)

	Code **DE/0000047823**		
	Bezeichnung / Name **MedPath GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Bayern**
	Ort / City **München**		Postleitzahl / Postal code **80807**
	Straße, Haus-Nr. / Street, house no. **Mies-van-der-Rohe-Strasse 8**		
	Telefon / Phone **089 189174474**		Telefax / Fax
	E-Mail / E-mail **info@medpath.pro**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Yiwu Xutai Outdoor Camping Enquipments Co.,Ltd**		
	Staat / State **CN**		
	Ort / City **Yiwu City,Zhejiang Province**		Postleitzahl / Postal code **322000**
	Straße, Haus-Nr. / Street, house no. **No.1,Huajin Road,Houzhai Industry Area**		
	Telefon / Phone **+86-579-85260959**		Telefax / Fax **+86-579-85260959**
	E-Mail / E-mail **15533342@qq.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Zheng Mei c/o MedPath GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Bayern**
	Ort / City **München**		Postleitzahl / Postal code **80807**
	Straße, Haus-Nr. / Street, house no. **Mies-van-der-Rohe-Strasse 8**		
	Telefon / Phone **089 189174474**		Telefax / Fax **089 5485 8884**
	E-Mail / E-mail **info@medpath.pro**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class ☒ I ☐ I - steril / sterile ☐ I - mit Messfunktion / with measuring function ☐ I - steril und mit Messfunktion / sterile and with measuring function ☐ I - Wiederaufbereitung / Reprocessing ☐ I - steril und Wiederaufbereitung / sterile and reprocessing ☐ I - mit Messfunktion und Wiederaufbereitung / with measuring function and reprocessing ☐ I - steril und mit Messfunktion und Wiederaufbereitung / sterile and with measuring function and reprocessing ☐ IIa ☐ IIb ☐ III ☐ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 ☐ Aktives implantierbares Medizinprodukt / Active implantable medical device ☐ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Emergency Blanket**
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code **10-415**
	Nomenklaturbezeichnung / Nomenclature term **Decke**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	☐ Semikritische Medizinprodukte / Semicritical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B
	☐ Kritische Medizinprodukte / Critical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B ☐ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures ☐ Dampfsterilisation / Steam sterilisation ☐ Gassterilisation / Gas sterilisation ☐ Strahlensterilisation / Radiation sterilisation ☐ andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **München**

Datum
Date **2021-07-13**

Name
Zheng Mei

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone