BIOLOGICAL EVALUATION
TEST REPORT

For

Tattoo Cartridge Needles/ PMU Cartridge Needles

Model: 0803RLL, 0805RLL, 0807RLL, 0809RLL, 1003RLL, 1005RLL, 1007RLL, 1009RLL, 1011RLL, 1201RLL, 1203RLL, 1205RLL, 1207RLL, 1209RLL, 1211RLL, 1213RLL, 1214RLL, 1005RSL, 1007RSL, 1009RSL, 1011RSL, 1014RSL, 1203RSL, 1205RSL, 1207RSL, 1209RSL, 1211RSL, 1005CML, 1007CML, 1009CML, 1011CML, 1013CML, 1015CML, 1017CML, 1019CML, 1021CML, 1023CML, 1025CML, 1027CML, 1205CML, 1207CML, 1209CML, 1211CML, 1213CML, 1215CML, 1217CML, 1219CML, 1223CML, 1005MGL, 1007MGL, 1009MGL, 1011MGL, 1013MGL, 1015MGL, 1205MGL, 1207MGL, 1209MGL, 1211MGL, 1213MGL, 1215MGL, 1217MGL, 1219MGL, 1223MGL

Brand Name: PEPAX

Report No.: ENC2309041GZ98E1

Date of Issue: Sep. 6, 2023

Prepared For

Yiwu Wenmei Import & Export Co., Ltd

12/F Building 7, No.788 Cheng Dian South Road, Yiwu City, Zhejiang, China

Prepared By

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VERIFICATION OF CONFORMITY

Product Designation:	Tattoo Cartridge Needles/ PMU Cartridge Needles
Model:	0803RLL, 0805RLL, 0807RLL, 0809RLL, 1003RLL, 1005RLL, 1007RLL, 1009RLL, 1011RLL, 1201RLL, 1203RLL, 1205RLL, 1207RLL, 1209RLL, 1211RLL, 1213RLL, 1214RLL, 1005RSL, 1007RSL, 1009RSL, 1011RSL, 1014RSL, 1203RSL, 1205RSL, 1207RSL, 1209RSL, 1211RSL, 1005CML, 1007CML, 1009CML, 1011CML, 1013CML, 1015CML, 1017CML, 1019CML, 1021CML, 1023CML, 1025CML, 1027CML, 1205CML, 1207CML, 1209CML, 1211CML, 1213CML, 1215CML, 1217CML, 1219CML, 1223CML, 1005MGL, 1007MGL, 1009MGL, 1011MGL, 1013MGL, 1015MGL, 1205MGL, 1207MGL, 1209MGL, 1211MGL, 1213MGL, 1215MGL, 1217MGL, 1219MGL, 1223MGL
Model Difference:	All models have the same material as 0803RLL, except for different appearance and size
Brand Name:	PEPAX
Applicant:	Yiwu Wenmei Import & Export Co., Ltd
	12/F Building 7, No.788 Cheng Dian South Road, Yiwu City, Zhejiang, China
Manufacturer:	Yiwu Wenmei Import & Export Co., Ltd
	12/F Building 7, No.788 Cheng Dian South Road, Yiwu City, Zhejiang, China
Type of Test:	DELAYED-TYPE HYPERSENSIVITY TEST
Technical Standards:	EN ISO 10993-1:2020, EN ISO 10993-10:2021, EN ISO 10993-12:2021
File Number:	ENC2309041GZ98E1
Date of test:	Aug. 5, 2023 – Sep. 6, 2023
Deviation:	None
Condition of Test Sample:	Normal

The above equipment was tested by East Notice Certification Service Co., Ltd. for compliance with the requirements set forth in MEDICAL DEVICES:GENERATL Directive 93/42/EEC and the Technical Standards mentioned above.
Should any objections to the test reports occurred, should submit it to the Company within ten days since the issuing of the report, Fail to accept.
The test results of this report relate only to the tested Sample identified in this report.

Checked By Yemig
Yemig Sep. 6, 2023

Authorized By Ray Zhou
Ray Zhou Sep. 6, 2023

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SUMMARY

A toxicological study was performed to evaluate the biocompatibility of the test substance Tattoo Cartridge Needles/ PMU Cartridge Needles, at this purpose the following test was carried out:

- test standards: EN ISO 10993-1:2020, EN ISO 10993-10:2021, EN ISO 10993-12:2021

The analytical test was accomplished on the materials of Metal needle and Plastic shell which constitute the device and are in contact with the human skin:

Two eluates of the test substance were prepared both in vegetable oil and in physiological solution in order to perform the delayed-type hypersensivity test.
In static condition the eluates of the test material were performed by immersing the test material in both physiological solution and vegetable oil in order to reach weight/volume ratios and surface/volume ratios of:

- 0.2 g /ml for the Plastic shell
- 0.2 g/ml for the Metal needle

The test sample was then incubated for 72 hours at 37^0C ±1^0C, after this period, has been done a pool of eluates.
For each elution 15 guinea pigs were used, 10 treated with the eluate of the test substance and 5 using as control treated with extraction liquid only.

The skin sensitisation test had 2 phases, induction phase and challenge phase.
During the induction phase the group of 10 treated guinea pigs were treated with 3 double intradermal injections as follows:
1st Freud Complete Adjuvant in distilled water (ratio 1:1)
2nd Elution of the test substance
3rd Elution of the test substance and FCA (ratio 1:1)
The control animals received the same pairs of injections, but in the 2nd injection only extraction liquid was administered (physiological solution or vegetable oil).
In the third injection, extraction liquid + FCA (ratio 1:1) was used.
After 3 days from the beginning of treatment on the all animals, a topical application, with slight massage, of 0.5 ml of Sodium Lauril Solfatum 10% was performed.
After 4 days from the intradermal injections, the test substance was applied (at a dose of 0.5 ml/animal). The application lasted 48 hours.
The same treatment was used on control guinea pigs using only extraction liquid.
After 7 days from the beginning of treatment the challenge phase was performed by applying 0.5 ml of the eluate on the left side and 0.5 ml of the eluates on the right side. The

bandage was left on for 24 hours. 24, 48 and 72 hours after the beginning of this phase, the tested and the control animals were observed.
Neither edema nor erythema were observed in the animals treated with the test substance eluate prepared in physiological solution. and in vegetable oil.
No abnormalities were observed in the animals used as control.

On the basis of the results obtained for all tested components, interpreted according to EN ISO 10993-10:2021 the test substance Tattoo Cartridge Needles/ PMU Cartridge Needles must be considered **NOT SENSITIZING**.

INTRODUCTION

This study has been carried out on behalf of Metal needle and Plastic shell on the product Tattoo Cartridge Needles/ PMU Cartridge Needles.

The study was performed at the Test Facility ENC-lab of East Notice Certification Service Co., Ltd.

TEST	START	END	RESEARCHER
delayed-type hypersensivity test	Aug. 5, 2023	Sep. 6, 2023	Sam Liu

BIBLIOGRAPHY

1. EN ISO 10993-10:2021
Biological evaluation of medical devices
Part 10: Tests for irritation and delayed-type hypersensivity

FILING

The study program, all raw data and a copy of the final report are filed in the archives of ENC-lab. for ten years after the issuing of the final report.
No retained sample will be kept.
At the end of the conservation period, the Sponsor may request an extension of the conservation of all or part of the substances for a further period, or their restitution. A suitable agreement shall be drafted in this case.

PROCEDURES

All procedures used during this study are recorded in the ENC-lab Procedures Manual.

TEST SUBSTANCE DESCRIPTION

The test substance is a device consisting of Metal needle and Plastic shell intended to human use in contact with the skin.

Name: Tattoo Cartridge Needles/ PMU Cartridge Needles

ANALYSED SAMPLE

The analysed sample, representative of the test substance, is identified by the following numbers:

Name:	Tattoo Cartridge Needles/ PMU Cartridge Needles
Test Model:	0803RLL
Date of production:	Jul. 15, 2023
Shelf life:	2 years
Receiving date:	Aug. 5, 2023
Registration number:	N/A

DELAYED-TYPE HYPERSENSIVITY TEST

EXPERIMENTAL PROCEDURE

1. TEST METHOD

1.1 Characterisation

Species:	Albino guinea pigs
Strain:	Hartley
N.:	30
Weight:	300 - 400 g at the arrival at the Centre
Sex:	female
Supplier:	Guangzhou Juyuan Breeding Farm

1.2 Caging

The animals were caged, in groups of ten, in transparent polycarbonate cages (dimensions: 590x385x200h mm).
The housing room was lighted with fluorescent lamps 12 hours for day.
Room temperature and humidity were regulated by a conditioning plant and were monitored daily.
Recordings of the housing conditions are being retained in ENC-lab files.

1.3 Cleaning and disinfection

The cages and the housing room were cleaned before the animals were accommodated, then disinfected periodically.

1.4 Feeding

Animals have been fed with standard pellet complete diet supplied by the authorized breeder Susan.

1.5 Watering

Filtered tap water from local network was supplied ad libitum from an automatic watering system.

1.6 Quarantine

Before allocation to the study, the animals were kept in quarantine for one week.
During this period they were observed daily.
At the end of the quarantine period the animals were carefully examined in order to evaluate their suitability for the study.

2. TEST SAMPLE PREPARATION

The eluates of the test substance were prepared in static conditions by immersing:

- Plastic shell (48.8g) into 244 ml of both eluants in order to reach a weight/volume ratio of 0.2 g/ml.
- Metal needle (52.6g) into 263 ml of both eluants in order to reach a weight/volume ratio of 0.2 g/ml.

The test samples were then incubated for 72 hours at 37^0C ±1^0C, after this period, two pools of eluates have been done.

3. EXPERIMENTAL DESIGN

Experimental design consisted of two groups (treated) of 10 animals treated with extract in vegetable oil and in physiological solution of test substance (group 1-2) and two group (control) of 5 control animals treated with only vegetable oil or physiological solution (group 3-4). The animals were divided in groups as follows:

GROUP	INDUCTION		CHALLENGE TOPIC APPLICATION
	Intradermal injection	Topic application	
1	1. Extract in physiological solution 2. Extract in physiological solution + FCA 3. FCA	Extract in physiological solution	Right side: Extract in physiological solution
			Left side: Physiological solution
2	1.Extract in freshly refined vegetable oil 2.Extract in freshly refined vegetable oil+ FCA 3.FCA	Extract in vegetable oil	Right side: Extract in vegetable oil
			Left side: Vegetable oil
3	1. Physiological solution 2. Physiological solution + FCA 3. FCA	Physiological solution	Right side: Extract in physiological solution
			Left side: Physiological solution
4	1. Freshly refined vegetable oil 2. Freshly refined vegetable oil + FCA 3. FCA	Vegetable oil	Right side: Extract in vegetable oil
			Left side: Vegetable oil

The animals allocated to the study were selected randomly from those suitable, available at that time.

4. TREATMENT

4.1 Skin preparation

24 hours before testing, fur was removed by shaving a 50 cm^2 wide area on the back of the animals.

4.2 Administration

The test consisted of an induction phase and a challenge phase.

Induction phase

Day 0 - treated group

Three pairs of 0,1 ml intradermal injections were made in the intrascapolar region of each animal, on each side of the midline, according to the following scheme:

1) FCA in distilled water (ratio 1:1)
2) Elution of test substance
3) Elution of test substance + FCA (ratio 1:1)

Day 0 - control group

Three pairs of 0,1 ml intradermal injections were made in the intrascapolar region of each animal, on each side of the midline. The content was:

1) FCA in distilled water
2) Extraction liquid
3) Extraction liquid + FCA (ratio 1:1)

Day 3 - treated group and control group

After 6 days the beginning of treatment on the all animals a topical application, with slight massage of 0,5 ml of Sodium Lauril Solfatum 10%, was made.

Day 4 - treated group

Seven days after the intradermal injections had been made, 0,5 ml of the elution of the test substance were applied to each animal and held in place with an occlusive patch. The application was made on area caudally to the area of injection.
The dressing was left in place for 48 hours.

Day 4 - control group

The same treatment was performed on the control group, using vegetable oil and physiological solution instead of the test substance.

Challenge

Day 7 - treated and control groups

An occlusive patch with 0,5 ml of eluate of the test substance was applied to the right side and to the solvent to the left side.

The dressing was left in place for 24 hours.

OBSERVATIONS

On the 3rd day (24 hours after removal the patch), and the 4th day (48 hours after removal the patch) and the 5th day (72 hours after removal the patch) of tests all the animals treated and controlled were evaluated for a skin reaction.

The intensity of erythema and/or edema were evaluated according to the following scale:

Reaction	Grade
Erythema	
No erythema	0
Slight erythema	1
Well defined erythema	2
Moderate erythema	3
Severe erythema to slight eschar formation	4
Edema	
No edema	0
Slight edema	1
Well defined edema	2
Moderate edema	3
Severe edema	4

INTERPRETATION OF RESULTS

Both frequency and intensity of response were evaluated.
In case of positive reaction only in treated animals, the frequency of sensitization was considered, without taking into account the intensity of the response.

RESULTS

Neither edema nor erythema were observed in the animals treated with the test substance eluates prepared in physiological solution and in vegetable oil.
No abnormalities were observed in the animals used as control.

% sensitising guinea pigs treated with extract in physiological solution: 0%
% sensitised guinea pigs treated with extract in vegetable oil: 0%

The data concerning every single animal are reported in appendices 1 and 2.

CONCLUSIONS

On the basis of the results obtained for all tested components, interpreted according to EN ISO 10993-10:2021 the test substance Tattoo Cartridge Needles/ PMU Cartridge Needles must be considered **NOT SENSITIZING**.

APPENDICES

Appendix n.1: Skin reactions in treated animals with eluate

ANIMAL N.	TIME AFTER CHALLENGE APPLICATION					
	physiological solution					
	48 hours		72 hours		96 hours	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	0	0	0	0	0	0
7	0	0	0	0	0	0
8	0	0	0	0	0	0
9	0	0	0	0	0	0
10	0	0	0	0	0	0

ANIMAL N.	TIME AFTER CHALLENGE APPLICATION					
	vegetable oil					
	48 hours		72 hours		96 hours	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	0	0	0	0	0	0
7	0	0	0	0	0	0
8	0	0	0	0	0	0
9	0	0	0	0	0	0
10	0	0	0	0	0	0

Erythema

0= No erythema

Edema

0= No edema

Appendix n.2: Skin reactions in control animals treated with vegetable oil and physiological solution

ANIMAL N.	TIME AFTER CHALLENGE APPLICATION					
	physiological solution					
	48 hours		72 hours		96 hours	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0

ANIMAL N.	TIME AFTER CHALLENGE APPLICATION					
	vegetable oil					
	48 hours		72 hours		96 hours	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0

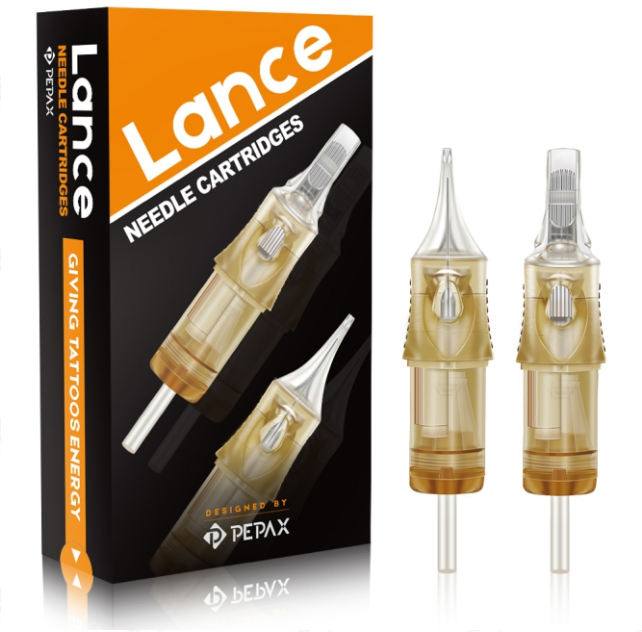
Erythema

0= No erythema

Edema

0= No edema

Appendix n.3: Photograph(s) of sample



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