

## **Certification of Conformity**

## **EU-MEDICAL DEVICES DIRECTIVE-93/42/EEC**

Registration No.: ENC2309041GZ98

Applicant : Yiwu Wenmei Import & Export Co., Ltd

Applicant Address : 12/F Building 7, No.788 Cheng Dian South Road, Yiwu City,

Zhejiang, China

Product Designation : Tattoo Cartridge Needles/ PMU Cartridge Needles

Model Number : 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

Manufacturer : Yiwu Wenmei Import & Export Co., Ltd

Manufacturer Address : 12/F Building 7, No.788 Cheng Dian South Road, Yiwu City,

Zhejiang, China

The submitted products have been tested by us with the listed standard and found in compliance with the Medical Devices Directive 93/42/EEC and following European Standards:

Requirement	Applied Standards	Test Report No.
DELAYED-TYPE HYPERSENSIVITY	EN ISO 10993-1:2020	ENC2309041GZ98E1
	EN ISO 10993-10:2021	
	EN ISO 10993-12:2021	

Test result: The submitted sample did not cause skin irritation or allergic sensitization.

This certificate is based on an evaluation of a sample of the above mentioned product. Technical report and documentation are at the licence applicant's disposal. This certificate does not imply assessment of the series-production of the product. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

CE

Ray Zhou / General Manager Date of Ssue: Sep. 6 2023

East Notice Certification Service Co., Ltd.