





TEST REPORT

REPORT NO.: CTNT230425004



Product name: Intraoral Digital Impression Instrument

Model No.: PANDA smart p, PANDA smart y

Applicant: Ziyang Freqty Medical Equipment Co., Ltd.

Test procedure: Entrustment Test

Shenzhen Zhongwei Festing Fechnology Co., Ltd.



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TEST REPORT 21CFR 1040.10

Performance standards for light-emitting products-Laser products 21CFR 1040.11

Specific purpose laser products

Report Number.....: CTNT230425004

Date of issue....: June 9, 2023

Shenzhen Zhongwei Testing Technology Co., Ltd.

Room 1A106, 1/F., No.109, Lijia Road, Henggang, Henggang

Name of Testing Laboratory

Street, Longgang District, Shenzhen, Guangdong, China

preparing the Report.....: Tel: 086-755-28680489

E-mail: admin@ctnt-cert.com
Web: www.ctnt-cert.com

Applicant's name...... Ziyang Freqty Medical Equipment Co., Ltd.

Floor 2-3, unit 7, building 3, No. 222, West Section 3, outer ring road,

Yanjiang District, Ziyang City, Sichuan Province, P.R. China

Manufacturer's name...... Ziyang Freqty Medical Equipment Co., Ltd.

Floor 2-3, unit 7, building 3, No. 222, West Section 3, outer ring road,

Yanjiang District, Ziyang City, Sichuan Province, P.R. China

Test specification:

Standard.....: 21CFR 1040.10 & 21CFR 1040.11

Test procedure....: Entrustment Test

Non-standard test method.....: N/A

Test Report Form No.....: 21CFR 1040.10 & 21CFR 1040.11

Test Report Form(s) Originator....: 1.0

Master TRF.....: CTNT

General disclaimer:

The test results presented in this report relate only to the object tested.

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Test item description.....: Intraoral Digital Impression Instrument

Trade Mark....: N/A

Model/Type reference.....: PANDA smart p, PANDA smart y

Ratings..... 5V=0.9A

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
Laboratory Name	Shenzhen Zhongwei Testing Technology Co., Ltd.	
Testing location/ address:	Room 1A106, 1/F., No.109, Lijia Road, Henggang, Henggang Street, Longgang District, Shenzhen, Guangdong, China	
Tested by(Test Engineer):	Rock Zhou	Rock Zhou
Reviewed By(Supervisor):	Airan Lu	Airan Lu
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List of Attachments (including a total number of pages in each attachmen

Approved by(Chief Engineer).....: | Flight Lee

- Photo document
- Test data diagram

Summary of testing:

Tests performed (name of test and test clause):

Determination of the result includes consideration of measurement uncertainty from the test equipment and methods.

According to the test of 21CFR 1040.10&21CFR 1040.11

Performance standards for light-emitting products-Laser products. This product is complied with the requirements of Class I. The maximum output power of the product is 96.41 µ W.

Testing location:

Shenzhen Zhongwei Testing Technology Co., Ltd. Room 1A106, 1/F., No.109, Lijia Road, Henggang, Henggang Street, Longgang District, Shenzhen, Guangdong, China

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Test item particulars.....:

Supply Connection.....: Powered by external adapter