EC Certificate Production Quality Assurance System FI20/07005

The management system of

Ziyang Freqty Medical Equipment Co., Ltd.

Zone A, B, C, 4 Floor,
Building A, No. 3, Xiandai Road,
Ziyang, Sichuan,
P.R.China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex V

Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

For the following products

Intraoral digital impression instrument

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 11 March 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue1. Certified since 3 March 2020
This certification is based on decision: FI20/07006P0

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

Seppo Vahasalo
Notified Body Manager

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Attachment 1 to SGS Fimko Ltd. EC certificate FI20/07005 Issue 1

Manufacturer	Ziyang Freqty Medical Equipment Co., Ltd.
Address	Zone A, B, C, 4 Floor, Building A, No. 3, Xiandai Road, Ziyang, Sichuan, P.R.China
Activity and Medical Device Product Category	93/42/EEC Annex V Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements Intraoral digital impression instruments

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Trademark(s) and Model(s)/type(s)
Intraoral Digital Impression Instrument	Im	PANDA P1
Intraoral Digital Impression Instrument	Im	PANDA P2

DECISION

11 March 2020

FI20/07006P0

Ziyang Freqty Medical Equipment Co., Ltd.
Zone A, B, C, 4 Floor,
Building A, No. 3, Xiandai Road,
Ziyang, Sichuan,
P.R.China

EC-certification application 19/122-0, dated 2019-08-13

Subject	Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex V Section 3, restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.
Manufacturer	Ziyang Freqty Medical Equipment Co., Ltd. Zone A, B, C, 4 Floor, Building A, No. 3, Xiandai Road, Ziyang, Sichuan, P.R.China
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Intraoral Digital Impression Instrument	PANDA P1	Im
Intraoral Digital Impression Instrument	PANDA P2	Im

Justification	SGS Fimko Ltd has assessed manufacturer's quality management system and products regarding the aspects of manufacture concerned with the conformity of the devices with metrological requirements. Quality management system and products meet the requirements of Annex V of Medical Device Directive 93/42/EEC. The decision is based on audit report(s) 296815, dated 2019-10-09. The manufacturer has signed the undertaking to follow the obligations of Annex V of the Directive 93/42/EEC.
Certificate related to decision	FI20/07005, Issue 1
Attachment to certificate	Attachment 1
Valid until	This decision is valid until 02 March.2025 providing the requirements of the certification are fulfilled.
Date	Helsinki, 11 March 2020

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd, Notified Body 0598