DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name:SUNGO EUROPE B.V.

Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

SRN: NL-AR-000000247

Manufacturer

Name: Ziyang Freqty Medical Equipment Co., Ltd.

Address: Floor 2-3, unit 7, building 3, No. 222, West Section 3, outer ring road, Yanjiang District, Ziyang City, Sichuan Province, China

SRN: CN-MF-000019421

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

ISO 13485:2016 ISO 14971:2019
ISO 15223-1:2021 ISO 20417:2021
IEC 60601-1:2005/AMD2:2020
IEC 60601-1-2:2014+A1:2020
IEC 60825-1:2014 IEC 62471:2006
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 CSV
IEC 62366-1:2015/AMD1:2020
IEC 62304:2006/AMD1:2015
ISO 10993-1:2018 ISO 10993-5:2009
ISO 10993-10:2021 ISO 10993-23:2021

Remark

The declaration of conformity is valid in connection with the release technical document ZYPT-CE-24.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: Intraoral Digital Impression Instrument

Model: PANDA smart p、PANDA smart y

GMDN: 63669

EMDN: Z11030402

Basic UDI-DI: 697513623PTPANDA001M9

Classification: Class I

Rule: Rule 5, Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: 2024.01.01

Ao Mingwu

Position: General Manager Place: Ziyang / China