DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO EUROPE B.V.
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 15223-1: 2021
ISO 10993-5:2009 ISO 10993-10:2021
ISO 10993-23:2021
EN ISO 14971: 2019 EN ISO 20417: 2021
IEC 60601-1:2005+A1:2012
EN 60601-1-2:2014+A1:2021
IEC 60825-1:2014 IEC 62471:2006
IEC 60601-1-6:2010+A1:2013
IEC 62366-1:2015 IEC 62304:2015

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: 2023.2.27

Ao Mingwu

Position: General Manager Place: Ziyang / China