



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

Conformity Assessment

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

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN 60601-1-2:2015
EN 60601-1:2006+A12:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z119008-01.

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.

Manufacturer

Name: Shenzhen Beacon Display Technology Co., Ltd.

Address: 15F, Building 6, Hengda Shishang Huigu(East), Fulong Road,Dalang Subdistrict, Longhua, Shenzhen, 518109 , P.R. China

SRN: CN-MF-000008774

Product Information

Name: LCD Monitor

Model: See annex

EMDN: Z119008

Basic UDI-DI: 697002782001FH

Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Intended Use: The monitor is intended to be used in displaying and viewing digital images, for review and analysis by trained medical practitioners.

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: 2021.10.11

Position: GM

Place: Guangdong/China



Annex

Product Name	Model	EMDN	Basic UDI-DI
LCD Monitor	C22S+、C22SP+、C24S+、G22S+、G22SP+、G23S+、G23SP+、 C32S+、C32SP+、G32S+、G32SP+、C53S+、C53SP+、G52S+、 G52SP+、G53S+、G53SP+、C43W+、C44W+、C61W+、 C81W+、C82W+、C83W+、C85W+、C86W+、C145T、C14S、 G11S、C22W、C22WT、C23W、C23WT、C24W、C24WT、 M553T、M652T、M862T、M982T、E150、E190、E2421、 E2422、E2721、S2421P、S271P、S272P、S273P、S2785P、 S3281P、S3285P、S3180P、S421、S551、S5583P、S5580P、 PV26、PV27、S3221P、S3181P、U2221、S1001T、 M8681T、C411W、HL2316SHA、HL2316SHTB、 HL2416SH、HL2416SHT S556、S556P、SP2421T、SP5581T、SP5581P、S3285P-3D、 S3221P-3D、C1216W、C610W、C616W、C811W、C810RT、 C810WT、C811RT、C811WT、HL2316SL、HL2416SL、C310S、 C510S、G510S、C316S、C516S、G516S、G310S、G316S、 C821W E2420、S2720P、S2780P、S3282P、S3286P、S4385P、 S5586P、S3286P-3D、SP6582P、SP6582T、SP3222T、 SP3222P、P2740、P2780、P3280、C821WT、C822W、 C822WT	Z119008	697002782001FH

Signature: 

Date: 2020.10.11

Position: GM

Place: Guangdong/China

