

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Shanghai PAX Medical Instrument Co., Ltd.

Building 3, No. 438 Fulian Two Road, Baoshan District,
Shanghai 201906, China

Trademark:

PANALEX

SRN:

CN-MF-000027540

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

DIMDI NO.:

DE/0000047823

SRN:

DE-AR-000000087

Product name:

Operating Light

Product Model/Type:

PANALEX Series

PANALEX 1 、 PANALEX 1 (M) 、 PANALEX 1
(W) 、

PANALEX 2 、 PANALEX 3 、 PANALEX 4 、
PANALEX-A 、 PANALEX-B 、 PANALEX-C 、
PANALEX-D 、 PANALEX-E 、 PX350 、 PX350 (M) 、
PX350 (W)

Basic UDI:

697567880OL001QX

Classification acc. to MDR Ax. VIII:

Class I, rule 13

Applied Standard & Common Specification:

EN 60601-1:2006+AC:2010+A1:2013, EN 60601-2-41:2009,
EN 60601-1-2:2015

Conformity assessment procedure: Annex II + Annex III of Regulation (EU) 2017/745 MDR;
We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products
meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting
documentations are retained under the premises of the manufacturer.

Sign for and behalf of the manufacturer:

General Manager

Date and Place:

09. 08. 2022 Shanghai, China

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Shanghai PAX Medical Instrument Co., Ltd.
Building 3, No. 438 Fulian Two Road, Baoshan District,
Shanghai 201906, China

Trademark: PANALEX

SRN: CN-MF-000027540

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

DIMDI NO.: DE/0000047823

SRN: DE-AR-000000087

Product name: Operating Table

Product Model/Type: DS-II Series: DS-IIA, DS-IIC, DS-IIE, DS-IIF,
DS-IIK, DS-IIM, DS-IIN, DS-IIS,
CF280, CF380, CFT-C8, L7

Basic UDI: 6975678800T001SP

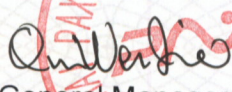
Classification acc. to MDR Ax. VIII: Class I, rule 13

Applied Standard & Common Specification: EN 60601-1:2006+AC:2010+A1:2013, EN 60601-2-46:2011,
EN 60601-1-2:2015

Conformity assessment procedure: Annex II + Annex III of Regulation (EU) 2017/745 MDR ;

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Sign for and behalf of the manufacturer:


General Manager

Date and Place:

09. 08. 2022 Shanghai, China

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Shanghai PAX Medical Instrument Co., Ltd.

Building 3, No. 438 Fulian Two Road, Baoshan District,
Shanghai 201906, China

Trademark:

PANALEX

SRN:

CN-MF-000027540

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

DIMDI NO.:

DE/0000047823

SRN:

DE-AR-000000087

Product name:

Operating Light

Product Model/Type:

PD Series: PD120、PD120 (M)、PD120 (W)、
PD120 (C)、PD160、PD160 (M)、PD160 (W)、
PD160 (C)、PD120/120、PD160/120、PD160/160、
PD120/120 (C)、PD160/120 (C)、PD160/160 (C)、
PML30、PML30 (M)、PML30 (W)、ELD 1、ELD
2、ELD 3、ELD 4

Basic UDI:

697567880OL002QZ

Classification acc. to MDR Ax. VIII:

Class I, rule 13

Applied Standard & Common Specification:

EN 60601-1:2006+AC:2010+A1:2013, EN 60601-2-41:2009,
EN 60601-1-2:2015

Conformity assessment procedure: Annex II + Annex III of Regulation (EU) 2017/745 MDR ;
We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products
meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting
documentations are retained under the premises of the manufacturer.

Sign for and behalf of the manufacturer:


General Manager

Date and Place:

09. 08. 2022 Shanghai, China