

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