# EU DECLARATIONOF CONFORMITY

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

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|---|---|
| **Manufacturer:** | Shanghai PAX Medical Instrument Co., Ltd.<br>Building 3,No.438 Fulian Two Road, Baoshan District, Shanghai 201906, China |
| **Trademark:** | PANALEX |
| **SRN:** | CN-MF-000027540 |
| **EuropeanRepresentative:** | MedPath GmbH<br>Mies-van-der-Rohe-Strasse8<br>80807 Munich, Germany |
| **DIMDI NO.:** | DE/0000047823 |
| **SRN:** | DE-AR-000000087 |
| **Product name:** | Operating Light |
| **Product Model/Type:** | PANALEX Series<br>PANALEX 1、PANALEX 1（M）、PANALEX 1（W）、<br>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,<br>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:

SHANGHAI PAX MEDICAL INSTRUMENT CO., LTD

General Manager

Date and Place:

09.08.2022, Shanghai, China

Digitally signed by Perminov Andrei
Date: 2024.04.19 11:12:44 EEST
Reason: MoldSign Signature
Location: Moldova