



EU Declaration of Conformity

In accordance with regulation 2017/745 EU on Medical devices

Manufacturer: **Chongqing Optec Instrument Co.,Ltd**

13-3, No.6, Fengqi Road, Caijiagang, Beibei District, Chongqing, China.

Authorized Representative: Tehoptimed SA, address: MD 2052 str. Maria Dragan 19A, Chisinau city, Republic of Moldova

Single Registration Number: TST20220770260-2EC

We the manufacturer, herewith declare under our sole representative that the following Medical Devices meets the requirements of the European Regulation (EU) 2017/745 (medical device class I).

Product Identification: Lab Instruments, Equipments

Medical Devices name/Trade Name : Microscope/CNOPTEC

Model reference :

B203, BXXX, SmartXXX, BKXXX, BDSXXX, SZXXX, MDSXXX, MITXXX, MDJXXX, LGYXXX.

Part Numbers:

Accessories : N/A

Medical Device Class : I

Conformity Assessment Procedure : according to

EN-IEC 61326-1:2021 Electricalequipment for measurement, control and laboratory use – EMC requirements

EN-IEC 61000-3-2:2019+A1:2021

EN 61000-3-3:2013/A2:2021

EMS-directive 2014/30/EU (electromagnetic contability)

MDR Directive 2017/745 (medical device class I)

Low voltage directive-2014-35-EU (electrical equipment)

Scope of application : This Declaration of Conformity is valid for all products manufactured until 2025-07-28.

Notified Body : Not Applicable

Certificate Number: TST20220770260-2EC

The product herewith complies with the requirements of the European directives and harmonized standards and carries the CE-marking accordingly.

Stamp and signature : Mr. Shen

Date : June 06, 2023.

