

Declaration of Conformity



Manufacturer:

Lianyungang TianNuo Optical Instrument Co.,Ltd
No.3 JinQiao Road, Dapu Industrial park
222000 Lianyungang, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Medical Device:

Trial Frame

Specification:

UTF-5080, STF-5470, UTF-4880, UTF-5080Pro

Single Registration Number:

CN-MF-000012433

Device Basic UDI-DI:

69450339TFF9

UMDNS Code:

15582

Classification-Annex VIII::

Class I,rule 1

Conformity assessment Route:

Regulation (EU) 2017/745 Annex XI PartA

Classification:

Class I with measuring function

Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, GERMANY

Identification number:

 0123

(EC)Certificate(s):

G21 069181 0010 Rev. 00

Exp. date:

26 Apr. 2028

EC REP

European Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY
Tel: 0086-021-65951371, 0049-40-2513175.
Fax: 0049-40-255726

Start of CE-marking:

27 Apr.2023

Place, Date of Declaration:

Lianyungang, Jiangsu, China, 7 March 2024

Signature:

Mr. Ge Xiaojun

Position

General manager



We, the manufacturer, here with declare that the stated medical device meet the transposition into national law, the provisions of Regulation (EU) 2017/745 on Medical Devices; All supporting documentation is retained at the premises of the manufacturer, and the manufacturer is exclusively responsible for the Declaration of Conformity.