Declaration of Conformity

For the following products:

Infrared Thermometer

(Product Name)

AOJ-20A, AOJ-20B, AOJ-20C, AOJ-20D, AOJ-20E, AOJ-20F, AOJ-20H, AOJ-20M, AOJ-20T (Model Designation)

Product Classification: Ila

CONFORMITY ASSESSMENT ROUTE: ANNEX V

Notified Body:

Company Name: TÜV SÜD Product Service GmbH

Company Address: Ridlerstraße 65, 80339 MÜNCHEN, Germany

European Representative:

Company Name: Share Info GmbH

Address: Heerdter Lohweg 83, 40549 Düsseldorf, Germany.

Basic UDI-DI: 697204011AOJ20X178

The following manufacturer is exclusively responsible for making this declaration that the above-mentioned product is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC as amended by 2007/47/EC) and all supporting documentation is retained at the premises of the manufacturer:

Shenzhen AOJ Medical Technology Co., Ltd

Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126, Shenzhen, China

Applied Standards:

EN ISO 14971:2012, EN60601-1:2006+A1:2013, EN 60601-1-2:2015, EN ISO10993-5:2009, EN 1SO10993-10:2010, ENISO 15223-1:2016, EN 60601-1-11:2015, EN60601-1-6:2010/A1:2015, EN 62366:2008/A1:2015, EN ISO 80601-2-56:2012, EN ISO13485:2016, EN62304:2006/A1:2015

Notified Body: TÜV SÜD Product service GmbH

Ridlerstr 65, D-80339 München, Germany

Identification Number: 0123

(EC) Certificate(s): G2 1037030001 Rev.00

Valid Until: 2024-05-26

Start of CE-marking: 2020-01-15
Place, Date of Issue: Shenzhen

Signature: Queena Cham york of sol

(Management Representative)