

DECLARACIÓN RESPONSABLE

Nuestra referencia **CV-40, TERMÓMETRO INFRARROJOS MODO SIN CONTACTO "DORTMUNT"**, está fabricado con los mejores materiales y sistemas de seguridad, asegurados en la Directiva Europea **93/42/EEC** on Medical Devices MDD, Annex V (Devices in Class Iia, lib or III) y expidiendo en certificado **CE 0123** por TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 08339 Munich, Germany, con N° **G2 103703 0001**
Rev. 00.



Visítanos en www.fepako.com

Habiendo pasado inspección sanitaria por el Ministerio de Sanidad y Consumo en materia de Sanidad Exterior, según Real Orden SPI/2136/2011, modificada por la Orden SSI/2375/2014.



En Cartagena, agosto de 2020

Colaboramos con



Reconocimiento
a la responsabilidad
ambiental



Universidad
Politécnica
de Cartagena



UCAM
UNIVERSIDAD
CATOLICA DE MURCIA

UIMP Cartagena
Universidad Internacional Menéndez Pelayo



Asociaciones y Entidades a las que pertenecemos



Declaration of Conformity

For the following equipment:

Infrared Thermometer

(Product Name)

AOJ-20A, AOJ-20B, AOJ-20C, AOJ-20D, AOJ-20E, AOJ-20F, AOJ-20H, AOJ-20M,

AOJ-20T, F101, F102, F103

(Model, Designation)

PRODUCT CATEGORY: MEDICAL DEVICE

is herewith confirmed to comply with the requirements set out in the Council Directive 2011/65/EU on the restriction of the use of certain hazardous substances in the electrical and electronic equipment

Applied Standards:

IEC 62474:2012, IEC 62321:2013, EN 62321:2009, EN 50581:2012, IEC/TR62476

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CE Mark:

The following representative in Europe is responsible for making this declaration:

Company Name: Share Info Consultant Service LLC Repräsentanzbüro

Address: Heerdter Lohweg 83, 40549 Düsseldorf

No. G2 103703 0001 Rev.00

The following manufacturer is responsible for making this declaration:

Company Name:


Shenzhen AOJ Medical Technology Co., Ltd

Company Address:

601, 6th floor, B2 Building, An'le Industrial Park, #172 Hangcheng Avenue,
Sanwei Community, Hangcheng Street, Bao'an, Shenzhen, China


(Name/Position)




(Date)

TUV SUD
ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆ CERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE ◆ CERTIFIKAT ◆ CERTIFICATE



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 103703 0001 Rev. 00

Manufacturer:

S. AOJ. M. T. Co., Ltd.

601, 6th floor, B2 Building
An'le Industrial Park
#172 Hangcheng Avenue, Sanwei Community, Hangcheng Street
Bao'an
518126 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Infrared Thermometer and Fetal Doppler

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:	GZ1940501
Valid from:	2020-01-15
Valid until:	2024-05-26

Date, 2020-01-15

Christoph Dicks
Head of Certification/Notified Body



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EC Certificate

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No. G2 103703 0001 Rev. 00

Facility(ies):

S. AOJ. M.T. Co., Ltd.
601, 6th floor, B2 Building, An'le Industrial Park, #172 Hangcheng
Avenue, Sanwei Community, Hangcheng Street, Bao'an, 518126
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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