



EC Certificate Full Quality Assurance System FI18/07003

The management system of

Shenzhen Pacom medical Instruments Co.,Ltd

On the eighth floor of B District,
B Building, No 5 Industry five road,
Jiangbian Community, Songgang, BaoAn District,
Shenzhen
P.R.China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC
on Medical Devices, Annex II (excluding Section 4)

For the following products
Digital Thermometers and Infrared Thermometers

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 27 April 2018 until 27 April 2023
and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 27 April 2021
Issue 1. Certified since 27 April 2018
This certification is based on decision: FI18/07003P0

Authorised by

Tom Törn, Certification Director
SGS Fimko Ltd., Notified Body 0598



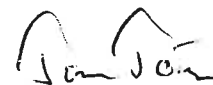
Attachment 1 to SGS Fimko Ltd. EC certificate FI18/07003 Issue 1

Manufacturer	Shenzhen Pacom medical Instruments Co.,Ltd
Address	On the eighth floor of B District, B Building, No 5 Industry five road ,Jiangbian Community. Songgang. BaoAn District, Shenzhen P.R.China
Activity and Product Category	93/42/EEC Annex II (excluding Section 4) Digital Thermometers and Infrared Thermometers

List of product names and the corresponding product type/model markings with trademarks/marketing names covered by this certificate:

Product Name	Class	Model/type nr. and Trademark(s)
Digital Thermometer	Ila	PC120 Flexible Digital Thermometer
Digital Thermometer	Ila	PC130 Flexible Basal Digital Thermometer
Digital Thermometer	Ila	PC160 Flexible Cartoon Digital Thermometer
Digital Thermometer	Ila	PC180 Digital Thermometer
Digital Thermometer	Ila	PC120T Basal Digital Thermometer
Infrared Thermometer	Ila	PC800 2 In 1 Infrared Thermometer
Infrared Thermometer	Ila	PC808 8 In 1 Infrared Thermometer
Infrared Thermometer	Ila	PC828 Non-Contact Infrared Thermometer
Infrared Thermometer	Ila	PC868 Non-Contact Infrared Thermometer

Authorised by



Tom Töm, Certification Director
SGS Fimko Ltd., Notified Body 0598

Date issued/revised: 27.04.2018

27 April 2018

FI18/07003P0

Shenzhen Pacom medical Instruments Co.,Ltd
 On the eighth floor of B District,B Building,No 5 Industry five road ,
 Jiangbian Community.Songgang.BaoAn District,
 Shenzhen P.R.China

EC-certification application 19.01.2018

Subject Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex II Section 3.

Manufacturer Shenzhen Pacom medical Instruments Co.,Ltd
 On the eighth floor of B District,
 B Building,No 5 Industry five road ,
 Jiangbian Community.Songgang.BaoAn District,
 Shenzhen
 P.R.China

Decision A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Digital Thermometer	PC120 Flexible Digital Thermometer	Ila
Digital Thermometer	PC130 Flexible Basal Digital Thermometer	Ila
Digital Thermometer	PC160 Flexible Cartoon Digital Thermometer	Ila
Digital Thermometer	PC180 Digital Thermometer	Ila
Digital Thermometer	PC120T Basal Digital Thermometer	Ila
Infrared Thermometer	PC800 2 In 1 Infrared Thermometer	Ila
Infrared Thermometer	PC808 8 In 1 Infrared Thermometer	Ila
Infrared Thermometer	PC828 Non-Contact Infrared Thermometer	Ila
Infrared Thermometer	PC868 Non-Contact Infrared Thermometer	Ila

Justification SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex II of Medical Device Directive 93/42/EEC. The decision is based on audit report(s) 288370.

The manufacturer has signed the undertaking to follow the obligations of Annex II of the Directive.

Certificate related to decision FI18/07003, Issue 1

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