

24 November 2016

Fli6/07024PO

Foshan Cingol Medical Instrument Co., Ltd
2nd Floor, The Warehouse of Guangdong YangChen CO.
Southern China Hardware Industrial Bast,
Danzao Town, Nanhai District,
Foshan City, Guangdong Province,
China

EC-certification application 18.12.2015

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

Manufacturer Foshan Cingol Medical Instrument Co., Ltd
2nd Floor, The Warehouse of Guangdong YangChen CO.
Southern China Hardware Industrial Bast,
Danzao Town, Nanhai District,
Foshan City, Guangdong Province,
China

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

Product	Model	Class
Dental unitlla	X1	
Dental unitlla	X3	
Dental unitlla	X5	
Dental unitlla	X9	

Justification SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex V of Medical Device Directive 93/42/EEC. The decision is based on audit report(s) 284555.

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

Certificate related to decision FM 6/07022, issue 1 ..

Attachment to certificate Attachment 1, issue 1.

Valid until This decision is valid until 24.11 2021 providing the requirements of the certification are fulfilled.

Date Helsinki, 24.1 12021



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

Business ID 0978538-5

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**SGS**EC Certificate Production Quality Assurance System FM
6/07022

The management system of

Foshan Cingol Medical Instrument Co., Ltd

2nd Floor, The Warehouse of Guangdong YangChen CO.
Southern China Hardware Industrial Bast,
Danzao Town, Nanhai District,
Foshan City, Guangdong Province,
CHINA has been assessed and certified as meeting the
requirements of Directive 93/42/EEC
on Medical Devices, Annex V

For the following products

Dental unit

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 24 November 2016 until 24 November 2021
and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 24 November 2019 Issue 1.
Certified since 24 November 2016

This certification is based on decision: FI 6/07024P0

Authorised by

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



SGS Fimko

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Ltd

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Business ID 0978538-5

SGS

Attachment 1 to SGS Fimko Ltd. EC certificate FM 6/07022, issue 1

Manufacturer	Foshan Cin ol Medical Instrument Co., Ltd
Address	2nd Floor, The Warehouse of Guangdong YangChen CO Southern China Hardware Industrial Bast, Danzao Town, Nanhai District, Foshan City, Guangdong Province, China
Activity and Product Cate o	93/42/EEC Annex V Dental unit

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

Product Name	Class	Model/ t e nr. and Trademark(s)
Dental unit	IIa	XI
Dental unit	IIa	
Dental unit	IIa	
Dental unit		

Authorised by

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

Date issued/revised: 24.112016, issue 1

Business ID 0978538-5

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