



EC Certificate Production Quality Assurance System FI15/07009

The management system of

Foshan Chuangxin Medical Apparatus Co., Ltd.

Eastern Industrial Development Zone, Xiadong Chongkou Pingliu Road,
Guicheng Street, Nanhai District, Foshan City, Guangdong Province,
P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on Medical Devices, Annex V

For the following products
Integral dental units

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 22 January 2019 until 3 December 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 3 December 2015
This certification is based on decision: FI15/07009P1

Authorised by

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd., Notified Body 0598



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Business ID 0978538-5

Member of the SGS

Group (SGS SA)



Foshan Chuangxin Medical Apparatus Co.,Ltd
Eastern Industrial Development Zone,
Xiadong Chongkou Pingliu Road,
Guicheng Street, Nanhai District,
Foshan City, Guangdong Province,
P.R.China

EC-certification application 2015-08-21

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

Manufacturer Foshan Chuangxin Medical Apparatus Co.,Ltd
Eastern Industrial Development Zone,
Xiadong Chongkou Pingliu Road,
Guicheng Street, Nanhai District,
Foshan City, Guangdong Province,
P.R.China

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

Product	Model	Class
Integral dental unit	CX-2305	Ila
Integral dental unit	CX-2311	Ila
Integral dental unit	CX-8000	Ila
Integral dental unit	CX-8900	Ila
Integral dental unit	CX-9000	Ila

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 re-certification audit report(s) 281759.

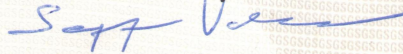
The manufacturer has signed the undertaking to follow the obligations of Annex V of the Directive 93/42/EEC.

Certificate related to decision FI15/07009, Issue 2

Attachment to certificate Attachment 1, Issue 2

Valid until This decision is valid until 3 December 2024 providing the requirements of the certification are fulfilled.

Date Helsinki, 22 January 2019


Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd, Notified Body 0598



Attachment 1 Issue 2 to SGS Fimko Ltd. EC certificate FI15/07009 Issue 2

Manufacturer	Foshan Chuangxin Medical Apparatus Co.,Ltd
Address	Eastern Industrial Development Zone, Xiadong Chongkou Pingliu Road, Guicheng Street, Nanhai District, Foshan City, Guangdong Province, P.R.China
Activity and Product Category	93/42/EEC Annex V Integral dental units

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)
Integral dental unit	Ila	CX-2305
Integral dental unit	Ila	CX-2311
Integral dental unit	Ila	CX-8000
Integral dental unit	Ila	CX-8900
Integral dental unit	Ila	CX-9000

Authorised by

Seppo Vahasalo
SGS Fimko Ltd., Notified Body 0598

Date issued/revised: 22.2.2019

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