

EC Certificate Production Quality Assurance System FI16/07015

The management system of

# Foshan Roson Medical Instruments Co., Ltd.

No.9 Henggui Mid-Road, Lianhe Industrial Zone, Luocun Shishan Town, 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  
**Dental Units**

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 12 May 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 9 September 2016

This certification is based on decision: FI21/07042P0

Authorised by

Jani Högman  
Certifier

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## Attachment 1 to SGS Fimko Ltd. EC certificate F116/07015 Issue 2

<b>Manufacturer</b>	Foshan Roson Medical Instruments Co., Ltd.
<b>Address</b>	No.9 Henggui Mid-Road, Lianhe Industrial Zone, Luocun Shishan Town, Nanhai District Foshan City, Guangdong Province P.R.China
<b>Activity and Medical Device Product Category</b>	93/42/EEC Annex V Dental Units

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

Medical Device	Class	Trademark(s) and Model(s)/type(s)
Dental Unit	Ila	KLT-6210
Dental Unit	Ila	KLT-6220

Foshan Roson Medical Instruments Co., Ltd.  
No.9 Henggui Mid-Road, Lianhe Industrial Zone, Luocun  
Shishan Town, Nanhai District  
Foshan City, Guangdong Province  
P.R.China

EC-certification application 15/033-2, dated 2021-05-04

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

**Manufacturer** Foshan Roson Medical Instruments Co., Ltd  
No.9 Henggui Mid-Road, Lianhe Industrial Zone, Luocun  
Shishan 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 Unit	KLT-6210	Ila
Dental Unit	KLT-6220	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 Audit Report(s) and Technical Documentation Review Report (s) 281489 date 02 April 2021 and 24 March.2021.

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

**Certificate related to decision** FI16/07015, Issue 2

**Attachment to certificate** Attachment 1

**Valid until** This decision is valid until 24 May 2024 providing the requirements of the certification are fulfilled.

**Date** Helsinki, 12 May 2021

Jani Högman, Certifier  
SGS Fimko Ltd, Notified Body 0598