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

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

Jani Högman
Certifier

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Attachment 1 to SGS Fimko Ltd. EC certificate FI16/07015 Issue 2

Manufacturer	Foshan Roson Medical Instruments Co., Ltd.
Address	No.9 Henggui Mid-Road, Lianhe Industrial Zone, Luocun Shishan Town, Nanhai District Foshan City, Guangdong Province P.R.China
Activity and Medical Device Product Category	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	IIa	KLT-6210
Dental Unit	IIa	KLT-6220

DECISION

12 May 2021

FI21/07042P0

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	IIa
Dental Unit	KLT-6220	IIa

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