

13 April 2016

F116/07003P0

Foshan Shunde Yeran Trading Co., Ltd
Room 504, No. 8 Guifeng Road
Daliang Shunde District
Foshan City
P.R. China

EC-certification application 21st August 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 Shunde Yeran Trading Co. Ltd
Room 504, No. 8 Guifeng Road
Daliang Shunde District
Foshan City
P.R. China

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

Product	Model	Class
Integral Dental Unit	VIC-V2	Ila
Integral Dental Unit	VIC-V3	Ila
Integral Dental Unit	VIC-V5	Ila
Integral Dental Unit	VIC-V6	Ila
Integral Dental Unit	VIC-V9	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) 281173 (27th Oct 2015 and 18th March 2016).

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

Certificate related to decision F116/07003

Valid until This decision is valid until 13th April 2021 providing the requirements of the certification are fulfilled.

Date Helsinki, 13th April 2016



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

EC Certificate Production Quality Assurance System FI16/07003

The management system of

Foshan Shunde Yeran Trading Co., Ltd

Room 504, No. 8 Guifeng Road
Daliang Shunde District
Foshan City
P.R. China

has been assessed and certified as meeting the requirements of

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

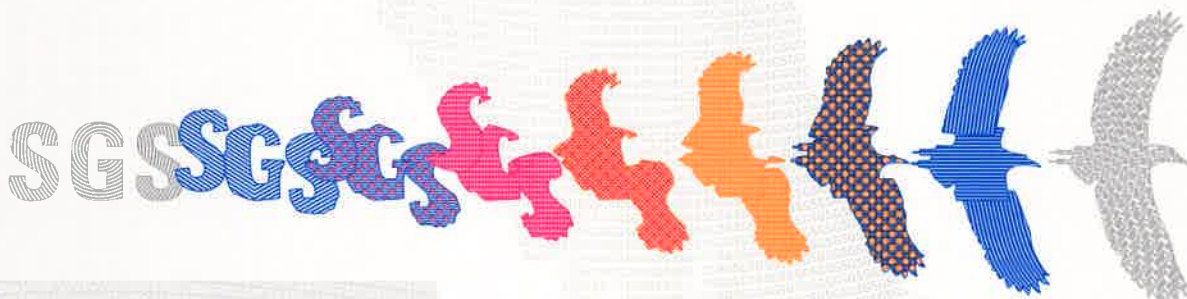
For the following products
Integral dental units

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 13 April 2016 until 13 April 2021
and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 13 April 2019
Issue 1. Certified since 13 April 2016
This certification is based on decision: FI16/07003P0

Authorised by

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



Attachment 1 to SGS Fimko Ltd. EC certificate FI16/07003

Manufacturer	Foshan Shunde Yeran Trading Co., Ltd
Address	Room 504, No. 8 Guifeng Road, Daliang Shunde District, Foshan City, 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	VIC-V2
Integral dental unit	Ila	VIC-V3
Integral dental unit	Ila	VIC-V5
Integral dental unit	Ila	VIC-V6
Integral dental unit	Ila	VIC-V9

Authorised by



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

Date issued/revised: 13.4.2016