EC Certificate Production Quality Assurance System FI16/07011

The management system of

Foshan ANYE Medical Apparatus Technology Co.,Ltd

Da Dang Gang Management Office
Muyuan Shishan Town, Nanhai District
Foshan City, Guang Dong
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

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

This certificate is valid from 18 March 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 19 July 2016
This certification is based on decision: FI21/07023P0

Authorised by

Jani Högman
Certifier

SGS Fimko Ltd., Notified Body 0598
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Attachment 1 to SGS Fimko Ltd. EC certificate FI16/07011 Issue 2

Manufacturer	Foshan ANYE Medical Apparatus Technology Co., Ltd.
Address	Da Dang Gang Management Office Muyuan Shishan Town, Nanhai District Foshan City, Guang Dong 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	AY-215A1, AY-215A2, AY-215A3, AY-215A5
Dental Unit	IIa	AY-215B1, AY-215B2, AY-215B3, AY-215B5
Dental Unit	IIa	AY-215C1, AY-215C2, AY-215C3, AY-215C5

DECISION

18 March 2021

FI21/07023P0

Foshan ANYE Medical Apparatus Technology Co., Ltd.
Da Dang Gang Management Office
Muyuan Shishan Town, Nanhai District
Foshan City, Guang Dong
P.R. China

EC-certification application 16/042-1, dated 2021-01-27

Subject	Recertification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex V.
Manufacturer	Foshan ANYE Medical Apparatus Technology Co., Ltd. Da Dang Gang Management Office Muyuan Shishan Town, Nanhai District Foshan City, Guang Dong P.R. China
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Dental Unit	AY-215A1, AY-215A2, AY-215A3, AY-215A5	IIa
Dental Unit	AY-215B1, AY-215B2, AY-215B3, AY-215B5	IIa
Dental Unit	AY-215C1, AY-215C2, AY-215C3, AY-215C5	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 file review report(s) 282938, dated 24 Jun. 2020 and 21 Dec. 2020. The manufacturer has signed the undertaking to follow the obligations of Annex V of the Directive 93/42/EEC.
Certificate related to decision	FI16/07011, 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, 18 March 2021

Jani Högman, Certifier
SGS Fimko Ltd, Notified Body 0598