EC Certificate Production Quality Assurance System FI21/07006

The management system of

Shenzhen Nile Biotechnology Co., Ltd

Room 503, Building B, Haikexing Industrial Park, No.16,
Baoshan Road, Langwei Village, Liulian Community,
Pingshan Office, Pingshan New District, Shenzhen,
Guangdong, 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

Mesh Nebulizers

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 02 April 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 02 April 2021
This certification is based on decision: FI20/07031P0

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 FI21/07006, Issue 1

Manufacturer	Shenzhen Nile Biotechnology Co., Ltd. ..
Address	Room 503, Building B, Haikexing Industrial Park, No.16, Baoshan Road, Langwei Village, Liulian Community, Pingshan Office, Pingshan New District, Shenzhen, Guangdong, P.R. China
Activity and Medical Device Product Category	93/42/EEC Annex V Mesh Nebulizers

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)
Mesh Nebulizers	IIa	UN100, UN101, UN200, UN300

02 April 2021

DECISION

FI21/07031P0

Shenzhen Nile Biotechnology Co., Ltd.
Room 503, Building B, Haikexing Industrial Park, No.16,
Baoshan Road, Langwei Village, Liulian Community,
Pingshan Office, Pingshan New District, Shenzhen,
Guangdong, P.R. China

EC-certification application 20/150-0, dated 2020-09-04

Subject	Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex V.
Manufacturer	Shenzhen Nile Biotechnology Co., Ltd. Room 503, Building B, Haikexing Industrial Park, No.16, Baoshan Road, Langwei Village, Liulian Community, Pingshan Office, Pingshan New District, Shenzhen, Guangdong, P.R. China
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Mesh Nebulizers	UN100, UN101, UN200, UN300	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) 299997, dated 18 Feb. 2021 and 08 Feb. 2021 The manufacturer has signed the undertaking to follow the obligations of Annex V of the Directive 93/42/EEC.
Certificate related to decision	FI21/07006, Issue 1
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, 02 April 2021

Jani Högman, Certifier
SGS Fimko Ltd, Notified Body 0598