



EC Declaration of Conformity



according to the Medical Devices Directive 93/42/EEC

Class I Medical Device
(non-sterile, without measuring function)

Manufacturer: Miraclean Technology Co., Ltd

Address: Music Community With The Village Of Yung Shue Ha Left Second And Third,
Longgang Street, Longgang District, Shenzhen, Guangdong, China

EC Representative: Wellkang Ltd
Suite B, 29 Harley Street, London W1G 9QR, UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Disposable Sampling Swab
	Type/model, identification of product allowing traceability (Where applicable)	FS740, PS740, P93050, 93050V, FS707, FS708, FS712, PS712
of class	according to annex IX of directive 93/42/EEC	Class I Medical Device (non-sterile, without measuring function)

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents	EN ISO 15223-1:2012	EN ISO13485:2016
	EN 1041:2008	EN 980
	EN ISO 14971:2009	EN 868-1
	EN ISO 10993	

Conformity assessment procedure

Module A (EC Declaration of Conformity (Annex VII) + Technical Files)

Notified Body (name & number)

NOT applicable

Certificate & number

Signed on: 2 **June** 2017. Place: Shenzhen, Guangdong, China

Signature (on behalf of the manufacturer)

Name of authorized signatory:
Position held in the company:
Company Seal/Stamp:

