

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Medikro Oy
Pioneerinkatu 3
FI-70800 Kuopio
Finland

Coverage of Certificate: Design, manufacture and final inspection

Product category: Spirometers and their accessories

Valid until: 22nd December 2015

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Tampere, 17th February 2014


Markku Helminen




Tuomas Toivonen




Certificate no.
VTT-C-10816-01-1056-507-14

Notified Body no. 0537:
VTT Expert Services Ltd.
P.O. Box 345 (Tekniikankatu 1)
FI-33101 TAMPERE
FINLAND
Tel.+358 20 722 111

Attachment 1 to the Certificate number: VTT-C-10816-01-1056-507-14

Manufacturer:	Medikro Oy Pioneerinkatu 3, FI-70800 Kuopio Finland		
Activity and product category:	Design, manufacture and final inspection of spirometers and their accessories		
Products:	The certificate covers the following products:		
	<i>Brand name</i>	<i>Model</i>	<i>Class</i>
	Spirometers (GMDN-code: 13680)		
	Medikro® Spirostar DX (Serial) Spirometer	M921	IIa
	Medikro® serial OEM Spirometer	M921-E	IIa
	D9-W-WA OEM Spirometer	M921-WA	IIa
	Medikro® Spirostar USB Spirometer	M929	IIa
	Medikro® USB OEM Spirometer	M929-E	IIa
	D9-W-WA USB OEM Spirometer (SpiroPerfect)	M929-WA	IIa
	Medikro® Nano	M913	IIa
	Medikro® Nano OEM	M913-E	IIa
	Medikro® Pro	M915	IIa
	Medikro® Pro OEM	M915-E	IIa
	410027 Spirometry Kit	M915-WA	IIa
	Medikro® Primo	M914	IIa
	Medikro® Primo OEM	M914-E	IIa
	Software (GMDN-code: 13680)		
	Medikro® Spirometry Software	M9831	IIa

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 93/42/EEC.

	<i>Brand name</i>	<i>Model</i>	<i>Class</i>
	Transducer (GMDN-code: 14117) SpiroSafe Disposable Flow Transducer	M9228, M9242, M9242-WA, M9256, M9256-WA	IIa
Date:	Tampere, 17 th February 2014   Markku Helminen  Tuomas Toivonen		