

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Medikro Oy
Kellolahdentie 27
FI-70460 Kuopio, Finland

Coverage of Certificate: Design, manufacture and final inspection

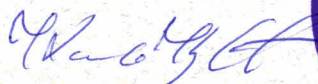
Product category: Spirometers and their accessories


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, 22nd December 2010




Kaarle Kylmä

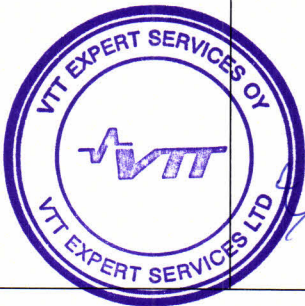

Seppo Lavonen

Certificate no.
VTT-C-6287-01-1056-425-10

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-6287-01-1056-425-10

Manufacturer:	Medikro Oy Kellolahdentie 27, FI-70460 Kuopio Finland			
Activity and product category:	Design, manufacture and final inspection of spirometers and their accessories			
Products:	The certificate covers the following products:			
	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	<i>Class</i>
	Spirometer	Medikro® SpiroStar DX (Serial) Spirometer	M921	IIa
	Spirometer	Medikro® serial OEM Spirometer	M921-E	IIa
	Spirometer	D9-W-WA OEM Spirometer (Spiro Perfect)	M921-WA	IIa
	Spirometer	Medikro® SpiroMaster MX Spirometer	M922	IIa
	Spirometer	Medikro® SpiroStar USB Spirometer	M929	IIa
	Spirometer	Medikro® USB OEM Spirometer	M929-E	IIa
	Spirometer	D9-W-WA USB OEM Spirometer (SpiroPerfect)	M929-WA	IIa
	Software	Medikro® Spirometry Software (variants Smart, Pro and Sense)	M9831	IIa
	Transducer	SpiroSafe Disposable Flow Transducer	M9228, M9242, M9242-WA	IIa
	Trainer	Inhalation Trainer (Easyhaler PIF-meter)	M9472	IIa
Date:	Tampere, 22nd December 2010			



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