

DECISION

on changes to the approved quality system as specified in Annex II, Section 3 of Council Directive 93/42/EEC concerning medical devices, or to the product range covered.

Decision no.:	VTT-C-2335-01-1056-309-07-P1
Manufacturer:	Medikro Oy, P.O.Box 54, FI-70101 Kuopio, Finland. Street address: Kellolahdentie 27, FI.70460 Kuopio, Finland
Date of manufacturer's notification:	24 th February 2009
Procedure and product category:	Design, manufacture and final inspection of spirometers and their accessories
Description of the changes:	<p>Change of existing product names and codes. No technical changes. The certificate covers now the following class IIa products:</p> <ul style="list-style-type: none"> • M921, Medikro® SpiroStar DX (Serial) Spirometer • M921-E, Medikro® Serial OEM Spirometer • M921-WA, D9-W-WA OEM Spirometer (SpiroPerfect) • M922, Medikro® SpiroMaster MX Spirometer • M929, Medikro® SpiroStar USB Spirometer • M929-E, Medikro® USB OEM Spirometer • M929-WA, D9-W-WA USB OEM Spirometer (SpiroPerfect) • M9831, Medikro® Spirometry Software (variants Smart, Pro and Sense) • M9228, M9242, M9242-WA, SpiroSafe Disposable Flow Transducer • M9472, Inhalation Trainer (Easyhaler PIF-meter)
The decision:	The manufacturer's quality system related to the aforementioned changes has been assessed and it still meets the requirements in Annex II of Medical Device Directive 93/42/EEC. The decision is based on change assessment report NB-1056-MR9 and the audit report no. NB-1056-A7.
Certificate related to the decision:	VTT-C-2335-01-1056-309-07
Validity:	This decision is valid until 22 nd December 2010 unless the validity of the related certificate is changed.
Date:	Tampere 29th June 2009



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

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