

## Declaration of Conformity

Manufacturer: n dd Medizintechnik AG  
Address: Technoparkstrasse 1  
CH-8005 Zürich, Switzerland

declares under its sole responsibility, that the product

Product designation: Disposable Flow Tube  
Product name: Spirette™

is in conformity with the essential requirements and provisions of Council Directive 93/42 EEC,  
is in conformity with the following standards transposing harmonized standards:

EN 1041:1998  
EN ISO 10993-1  
EN ISO 13485:2003  
EN ISO 14971:2000

is subject to the procedure set out in Annex II of Directive 93/42/EEC.

Zurich, October 30<sup>th</sup>, 2009

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A large, stylized handwritten signature in blue ink, consisting of several loops and flourishes.

E. Kleinhapfl  
Q-Management