

EC Declaration of Conformity

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

Herewith we declare our sole responsibility for the declaration of conformity.

We declare under our sole responsibility that the medical device:

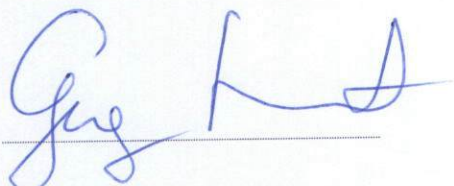
Product name: **Spirette™**
Product designation: **Flow tube (disposable)**
Model number: **2050-1, 2050-5, 2050-6, 2050-10, 2050-500**

Classified as: Class I
according to annex IX of directive 93/42/EEC

meets all provisions of the directive 93/42/EEC which apply to it.

Applied standards EN ISO 1041:2013
EN ISO 14971:2012
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN ISO 10993-18:2009

ndd Medizintechnik AG follows the procedure related to the EC declaration of conformity set out in Annex VII of Directive 93/42/EEC.



Georg Harnoncourt, CEO



Christian Buess, CTO

Zurich, 20.12.2018