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