EU 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 devices:

Product name:	Spirette EasyOne FlowTube
Product designation:	Breathing mouthpieces
Product type:	Pulmonary Function Testing Devices
Model number:	**Spirette**: 2050-0 (basic unit) 2050-1, 2050-5, 2050-6, 2050-10, 2050-1GE, 2050-5GE, 2050-1HS, 2050-5HS (packaging configurations) **EasyOne FlowTube**: 5050-0 (basic model) 5050-50, 5050-200, 5050-500, 5050-50MCK, 5050-200MCK (packaging configurations)
Classified as:	Class IIa according to annex IX of directive 93/42/EEC

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

Applied standards:	See List of Applied Standards
Authorised Representative:	**Johner Medical GmbH** Office Frankfurt Speicherstrasse 16 60327 Frankfurt am Main, Germany

ndd Medizintechnik AG follows the procedure related to the EC declaration of conformity set out in Annex II of Directive 93/42/EEC which involves the intervention of the Notified Body:

TÜV SÜD Product Service GmbH, Notified Body 0123
Ridlerstrasse 65, 80339 Munich, Germany

Validity of the Declaration of Conformity corresponds to the validity of the EC Certificate G1 005204 0002, Rev. 01.
This declaration of conformity covers the products that have been released for production from the date of issuance of this Declaration of Conformity onward.

Andreas Senn,
Director Quality, Regulatory Affairs & Clinical Affairs

Georg Harnoncourt,
CEO

Zurich, 25.May.2021