EU Declaration of Conformity

Manufacturer	**NDD Medizintechnik AG** Technoparkstrasse 1 CH-8005 Zürich, Switzerland
Product Family	Breathing Mouthpieces
Basic UDI-DI	764014219mouthpiece24
Single Registration Number	CH-MF-000015550
Authorized Representative	**NDD Medizintechnik GmbH** Endersbacher Strasse 49 DE-71334 Waiblingen Germany SRN: DE-AR-000032322
Product Trade Name & Catalogue Number	**Spirette:** 2050-0 (basic unit) 2050-1, 2050-5, 2050-10, 2050-1GE, 2050-5GE, 2050-1HS, 2050-5HS (packaging configurations) **EasyOne FlowTube:** 5050-0 (basic unit) 5050-50, 5050-200, 5050-500, 5050-50MCK, 5050-200MCK (packaging configurations)
CND code	Z12150185 Spirometry Instruments - Consumables
Classification	Class IIa according to (EU) 2017/745, Annex VIII, Rule 5
Common Specifications	See List of Applied Standards

We hereby declare our sole responsibility for the EU Declaration of Conformity.

The devices covered by this declaration are in conformity with the European Medical Device Regulation (EU) 2017/745 as well as other relevant Union legislations that make provisions for the issuing of a declaration of conformity.

ndd Medizintechnik AG follows the Conformity Assessment procedure based on a Quality Management pursuant to Regulation (EU) 2017/745, Annex IX, which involves the intervention of the Notified Body:

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

This Declaration of Conformity is applicable to all products listed and released after the Date of Issuance of this Declaration of Conformity, and is valid until the expiry date of the CE Certificate G10 005204 0004.

Andreas Senn,
Director of Quality Systems

Zurich, 30. May 2023

Michael Bencak,
CEO