EU Declaration of Conformity

Manufacturer	**ndd Medizintechnik AG** Technoparkstrasse 1 8005 Zürich, Switzerland
Product Family	Breathing Tubes
Basic UDI-DI	764014219BreathingTubes6L
Single Registration Number	n/a
Authorized Representative	**Johner Medical GmbH** Office Frankfurt Speicherstrasse 16, 60327 Frankfurt am Main, Germany
Product Trade Name & Catalogue Number	**Spirette M** (8mm): 2050-78, 2050-7 **Filter Adapter**: 2030-01, 2030-02, 2030-10, 2030-20, 2030-11, 2030-21, 2030-12, 2030-22 **Spirette FA Pro/LAB**: 2050-70, 2050-71, 2050-72, 2050-73
CND code	Z12150185 Spirometry Instruments - Consumables
Classification	Class I according to (EU) 2017/745, Annex VIII, Rule 1
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 procedure related to the EU Declaration of Conformity set out in Annex IV of Regulation (EU) 2017/745.

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 a revised Declaration of Conformity is issued.

Andreas Senn, Director
Quality & Regulatory Affairs

Zurich, 15. March 2021

Georg Harnoncourt, CEO

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