

EU Declaration of Conformity

Manufacturer NDD Medizintechnik AG

Technoparkstrasse 1

CH-8005 Zürich, Switzerland

Filter **Product Family**

764014219Filter2J **Basic UDI-DI**

Single Registration Number CH-MF-000015550

NDD Medizintechnik GmbH **Authorized Representative**

Endersbacher Strasse 49

DE-71334 Waiblingen, Germany

SRN: DF-AR-000032322

EasyOne Filter FT, 2091-422 **Product Trade Name &** EasyOne Filter SP, 2091-412 **Catalogue Number**

Z12150185 Spirometry Instruments - Consumables **CND** code

Class I according to (EU) 2017/745, Annex VIII, Rule 1 Classification

See List of Applied Standards **Common Specifications**

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.

Michael Bencak

CEO

Andreas Senn, Director Quality, Regulatory Affairs &

Clinical Affairs

DoC_EasyOne_Filter_V02, V02 Form: ID:7000029, Rev:00

t. Aug. 2023