

EU Declaration of Conformity

We, Hamilton Bonaduz AG, CH-7402 Bonaduz/Switzerland confirm that the following products:

Product name: Reagent Container

P/N:

56694-01	Reagent Container 60ml 28pcs, with lid
56694-02	Reagent Container 60ml (Black) 28pcs, with lid
194051	Reagent Container 60ml 28pcs
814323	Reagent Container 60ml 28pcs
194052	Reagent Container 120ml 12pcs
814324	Reagent Container 120ml 12pcs
235833	Reagent Container 120ml 12pcs
56695-01	Reagent Container 2T 200ml 10pcs, with lid
56695-02	Reagent Container 2T 200ml (Black) 10pcs, with lid
235838	Reagent Container 100x200ml without BC

meets the following EC directive



IVD Directive

98/79/EU

Applied company quality management systems

EN ISO 9001
EN ISO 13485

Certification Body

TÜV Rheinland LGA Products GmbH
Am Grauen Stein 29
D-51105 Köln-Poll, Germany

Applied standards:

Risk Management:

ISO 14971:2012

Labeling:

ISO 15223-1:2012
EN 980:2008

Hamilton Bonaduz AG


Andreas Wieland

CEO

Bonaduz, 10.8.2016