

CE Declaration of Conformity

Manufacture: Caretium Medical Instruments CO., Ltd
Beishan Industrial Park 7 th Floor Building 1, Beishan
Road, Yantian, Shenzhen 518083 China

EC-Representative: Prolinx GmbH
Brehmstr.56 40239 Dusseldorf Germany

Product: Microplate Washer

Model: KWP-100A,KWP-100

Classification (98/79/EC IVDD, Annex II): Other
Conformity Assessment Route: Annex III

We herewith declare that the above mentioned products meet IVDD 98/79/EC. All supporting documentations are retained under the premises of the manufacturer.

General applicable directive and standards:

Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning In Vitro Diagnostic Medical Devices (IVDD 98/79/EC).

Applied EN standards:

EN ISO 13485:2012/AC:2012, EN ISO 14971:2012, EN 61010-1:2010, EN 61010-2-101:2013, EN 61010-2-081:2002, EN ISO 17511: 2003, EN 13641: 2002, EN 62366:2008, EN 15223-1: 2016, EN 1041:2008.EN 61326-1:2013, EN ISO 18113-1:2011

Place , Date of Issue: Shenzhen, 2021-03-01

Signature:

Name of Authorized Signatory: Mr. Li Shoufu

Position Held in Company: Management Representative

