

EU DECLARATION OF CONFORMITY

We, **Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany**

declare on our own responsibility, that the medical device

Leica SM2010 R

complies with

- the essential requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1–37), Annex III

EN 61010-2-101:2017
EN ISO 14971:2012

Device classification: IVD general/other

Quality Management System: Certified according to EN ISO 13485:2016 and ISO 9001:2015

Manufacturing site: Leica Microsystems Ltd. Shanghai, Building 1, 258 Jinzang Road, China (Shanghai) Pilot Free Trade, 201206 Shanghai, People's Republic of China

Nussloch, 28.08.2019



Michael Späth
Director Operations



Robert Gröpp
RA/QA Manager