

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 TP1020

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
EN 61326-2-6:2013

Device classification: IVD general/other


- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88–110)

EN 50581:2012

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, 15.03.2019


Martin Laszak
Director Customer Service Core Histology


Robert Gropp
RA/QA Manager