

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 RM2235

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, Annex III

EN 61010-2-101:2017

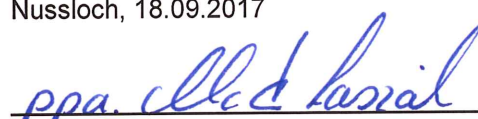
EN ISO 14971:2012

Device classification: IVD general/other

Quality Management System: Certified according to EN ISO 13485:2012 and ISO 9001:2008

Manufacturing site: Leica Microsystems Ltd. Shanghai, Building 1, 258 JinZang Road, Jinqiao Export&Processing Zone, Pudong, Shanghai 201206, PRC

Nussloch, 18.09.2017



Martin Laszak
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Robert Gropp
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