Advancing Cancer Diagnostics
Improving Lives

Leica
BIOSYSTEMS

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

ASP6025 S

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

Nussloch, 21.01.2020

Christoph Schwanke
HR Director CHS

Robert Gropp
RA/QA Manager

Rev. C