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

HistoCore SPECTRA ST

complies with the essential requirements of:

- 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

- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment (OJ L 153, 22.5.2014, p. 62–106)

  Final Draft ETSI EN 301 489-3 V2.1.1
  Draft ETSI EN 301 489-1 V2.2.0
  EN 300 330 V2.1.1
  EN 62311:2008
  EN 50665:2017

Quality Management System:	Certified according to ISO 13485:2016 and ISO 9001:2015
Manufacturing site:	Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany

Nussloch, 15.02.2019

ppa.

Martin Laszak
Director Customer Service

Robert Gropp
RA/QA Manager

Rev. B