

EU DECLARATION OF CONFORMITY

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

declare on our own responsibility, that the device

HistoCore LIGHTNING S

complies with

 Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357–374)

EN 61010-1:2010/A1:2019-02

 Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79–106)

EN 61326-1:2021-06

- 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)
- Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (OJ L 137, 4.6.2015, p. 10–12)

EN IEC 63000:2018-12

Quality Management System: Certified according to ISO 9001:2015

Manufacturing site: Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19,

69226 Nussloch, Germany

Nussloch, 23.09.2024

-Signed by:

Indras Edu

Signer Name: Andreas Eich
Signing Reason: I approve this document
Signing Time: 23-Sep-2024 | 08:03:28 PDT
CD5032D4531341BA80293CE9FF14CB78

Andreas Eich Senior Director Core Histology Signed by:

Signer Name: Maria Jernelid
Signing Reason: I approve this document
Signing Time: 24-Sep-2024 | 06:00:00 PDT
C496AFAE1E6D4B9AA38C2A0DD3FF8792

Maria Jernelid VP Global QA & RC