Advancing Cancer Diagnostics
Improving Lives

EU DECLARATION OF CONFORMITY

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

hereby declare under our sole responsibility that the medical device

Product and Trade name	**HistoCore SPECTRA ST**
Product	Automated Slide Stainer
Risk Class	A
Basic UDI-DI	010404918805129G
Single Registration Number	DE-MF-000021943
Product description	An automated mains electricity (AC-powered) laboratory instrument intended to be used to stain blood, tissue and/or other clinical specimens fixed to microscope examination slides, using one or more biological or cytochemical staining solutions in preparation for subsequent microscopic analysis. The device operates with minimal technician involvement and complete automation of all procedural steps.

meets the provision European legislation:

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (OJ L 117, 5.5.2017, p. 176–332). The procedure according to Annex II and Annex III of the above-mentioned regulation has been followed.

  EN IEC 61010-2-101:2022 + A11:2022
  EN ISO 14971:2019 + A11:2021
  EN IEC 61326-2-6:2021

- 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

- 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)

  EN 301 489-1 V2.2.3
  EN 301 489-3 V2.3.2
  EN 300 330 V2.1.1
  EN 50665:2017
  EN IEC 62311:2020
  EN 50364:2018
  EN 62369-1:2009

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

This declaration is effective for products placed on the market as of the date of issue.
Any modification of the device not authorized by Leica Biosystems will invalidate this declaration.

Nussloch, 01.07.2024

DocuSigned by:
Andreas Eich
Signer Name: Andreas Eich
Signing Reason: I approve this document
Signing Time: 12-Jul-2024 | 00:27:58 PDT
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Andreas Eich
Senior Director CH Nussloch

DocuSigned by:
Robert Gropp
Name des Unterzeichners: Robert Gropp
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 01-Jul-2024 | 16:52:40 MESZ
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Robert Gropp
RA/QA Director

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