Advancing Cancer Diagnostics
Improving Lives

Leica BIOSYSTEMS

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	**Leica ASP300 S**
Product	Tissue Processor
Risk Class	A
Basic UDI-DI	01040491880476A5
Single Registration Number	DE-MF-000021943
Product description	A mains electricity (AC-powered) laboratory instrument intended to be used for the processing of clinical tissue specimens [e.g., fixation (encapsulation in paraffin wax), dehydration, infiltration] in preparation for subsequent cytological or histological examination. The device may be a single unit or modular assembly. 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 61010-2-101:2017
  EN ISO 14971:2019
  EN 61326-2-6:2013

- 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

Quality Management System: Certified according to EN ISO 13485:2016 and ISO 9001:2015

Manufacturing sites: 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, 28.04.2022

Andreas Eich
Senior Director CH Nussloch

Robert Gropp
RA/QA Director

Rev. C