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

<table>
<thead>
<tr>
<th>Product and Trade name</th>
<th>Leica Autostainer XL (ST5010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
<td>Automated Slide Stainer</td>
</tr>
<tr>
<td>Risk Class</td>
<td>A</td>
</tr>
<tr>
<td>Basic UDI-DI</td>
<td>010404918804569X</td>
</tr>
<tr>
<td>Single Registration Number</td>
<td>DE-MF-000021943</td>
</tr>
<tr>
<td>Product description</td>
<td>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.</td>
</tr>
</tbody>
</table>

meets the provision European legislation:


  EN 61010-2-101:2017
  EN ISO 14971:2019
  EN 61326-2-6:2013


EN IEC 63000:2018


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
RAVQA Director