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 CM3050 S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
<td>Cryostat Microtome</td>
</tr>
<tr>
<td>Risk Class</td>
<td>A</td>
</tr>
<tr>
<td>Basic UDI-DI</td>
<td>010404918804709R</td>
</tr>
<tr>
<td>Single Registration Number</td>
<td>DE-MF-000021943</td>
</tr>
<tr>
<td>Product description</td>
<td>A precision cutting instrument contained within a temperature-controlled cabinet (i.e., a cryostat) intended to be used for the sectioning of rapidly-frozen tissue specimens without prior fixation to expedite subsequent in vitro diagnostic analysis of the tissue specimen.</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
RA/QA Director

Rev. B