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>HistoCore AUTOCUT</th>
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<tbody>
<tr>
<td>Product</td>
<td>Microtome</td>
</tr>
<tr>
<td>Risk Class</td>
<td>A</td>
</tr>
<tr>
<td>Basic UDI-DI</td>
<td>010404918805199W</td>
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<tr>
<td>Single Registration Number</td>
<td>DE-MF-000021943</td>
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<tr>
<td>Product description</td>
<td>A precision cutting instrument intended to be used to cut tissue sections, fixed in paraffin wax, into thin slices for subsequent in vitro diagnostic analysis. The device has a vertically-fixed knife which cuts through the paraffin block vertically, and a flywheel mechanism which cuts sections with each turn.</td>
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</tbody>
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meets the provision European legislation:

  
  EN 61010-2-101:2017
  EN ISO 14971:2012
  EN 61326-2-6:2013

  
  EN IEC 63000:2018


Manufacturing sites: Leica Microsystems Ltd, Shanghai, Floor 1, 2, 3A, 4A, and 6, Building T20-1 & Room 301, Building T20-5, 258 Jinzhang Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, PEOPLE’S REPUBLIC OF CHINA

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 Etch
Senior Director CH Nussloch

Robert Gropé
RA/QA Director