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 PEGASUS Plus</th>
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<tbody>
<tr>
<td>Product</td>
<td>Tissue Processor</td>
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<tr>
<td>Risk Class</td>
<td>A</td>
</tr>
<tr>
<td>Basic UDI-DI</td>
<td>01040491881488AK</td>
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<tr>
<td>Single Registration Number</td>
<td>DE-MF-000021943</td>
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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:


EN 61010-1-101:2017
EN ISO 14971:2012
EN 61326-1-2:2013


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 Eich
Senior Director CH Nussloch

Robert Gropp
RA/QA Director

Rev. D