DECLARATION OF CONFORMITY

We, Occlutech Tibbi Ürünler San. ve Tic. Ltd. Şti., AHL Serbest Bölgesi E-5 Blok, 34149 Bakırköy / İSTANBUL - TURKEY declare under our sole responsibility that medical device as listed below, meets all applicable requirements of the Directive 93/42/EEC.

Occlutech® Perimembranous Ventricular Septal Defect (PmVSD) Occluder

<table>
<thead>
<tr>
<th>Article No.</th>
<th>Distal Disc Diameter [mm]</th>
<th>Min. Weight Diameter [mm]</th>
<th>Max. Weight Diameter [mm]</th>
<th>Height [mm]</th>
</tr>
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<tbody>
<tr>
<td>84 VSD 04</td>
<td>12</td>
<td>4</td>
<td>8</td>
<td>5</td>
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<tr>
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<td>14</td>
<td>6</td>
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<td>5</td>
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<td>8</td>
<td>12</td>
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<td>84 VSD 12</td>
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<td>12</td>
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</tbody>
</table>

EU Authorized Representative: Occlutech GmbH
Wildenbruchstraße 15, 07745 Jena, Germany

Address of involved notified body to evaluate the conformity: DEKRA Certification GmbH, Handwerkstr. 15, D-70565 Stuttgart

Identification number of the notified body: 0124


Classification according to 93/42/EEC, Annex IX: Class III

Applied Rule for Classification according to 93/42/EEC, Annex IX: Rule VIII

GMDNS Code: 45418 (Cardiac Occluder)

Product identification allowing for traceability: Each lot of product is released for sale in accordance with records certifying compliance with product specifications.

Applicable harmonized standards: Product related List of Applicable Standards and Regulations (D11C06A02)

Validity of the Declaration of Conformity: From 2017-03-24 to 2022-02-23

İstanbul, 2017-03-24

CEO, Patrick J. Schnegelsberg
Occlutech Ltd.