Addition of labelling of MiniMACS Separator

<table>
<thead>
<tr>
<th>Product</th>
<th>REF</th>
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<tr>
<td>MiniMACS™ Separator</td>
<td>130-042-102</td>
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**Category of change:** Addition of labelling

**Current State:** The MiniMACS Separator is available for magnetic cell separations and therefore contains a powerful permanent magnet.

**Planned change:** New labeling material have to be introduced to indicate potential risks of the permanent magnet. Labelling of the handheld solenoid and its primary packaging will be updated.

**Justification/ Evaluation:** The labelling update is needed to draw attention to the possible risks for people with pacemakers using the MiniMACS Separator. Additionally, a the packaging design will be harmonized by adding the warning symbols and by introduction of a QR code. The QR code will allow the user to retrieve the datasheet.

There is no change of raw material or manufacturing process. Update of warning symbols leads to reduce risk of using the MiniMACS Separator. Therefore no impact on the performance, quality and safety of the affected product could be identified.

**Estimated Implementation**

Q4/2021

Please share, if applicable, this information with relevant staff in your organization. If there are any further questions, do not hesitate to contact us.

Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG