Change Notification
CC-22-0026

Design improvement of TheraSorb pro solution bags

<table>
<thead>
<tr>
<th>Product</th>
<th>REF</th>
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<tbody>
<tr>
<td>TheraSorb - NaCl pro</td>
<td>330-000-704</td>
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<tr>
<td>TheraSorb - Gly-HCl pro</td>
<td>330-000-703</td>
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<td>TheraSorb - PBS pro</td>
<td>330-000-682</td>
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<tr>
<td>TheraSorb - PA pro</td>
<td>330-000-781</td>
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Category of change: Design improvement

Current State: The current bag design comprises the features displayed below:

1) Long connecting tube at the upper end of the suction tube
2) Completely separated compartment to prevent suction tube from drifting
3) Row of punch holes for hanging the bag onto the apheresis unit
Design improvement of TheraSorb pro solution bags

Planned change:
The new bag design features the following improvements:

1) Shortened connector tubing to prevent kinking during storage and transit
2) Improved weld seam design to allow for better fluid exchange between the compartments and prevent suction failures
3) One single punch hole to guarantee optimal hanging angle on the apheresis unit
Design improvement of TheraSorb pro solution bags

Justification/Evaluation: There is no change of raw material. The manufacturing process is revised but no new hazards were identified. Therefore, no impact on the performance, quality and safety of the affected product could be identified.

Estimated Implementation Q4/2022

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

01.Mar.2022
Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG