Change Notification
CC-21-0279

Discontinuation of Luer/Spike Interconnector and Transfer Set Coupler/Coupler within the Asian/Pacific and Export markets

<table>
<thead>
<tr>
<th>Product</th>
<th>REF discontinued product</th>
<th>REF new product</th>
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<tbody>
<tr>
<td>Luer/Spike Interconnector</td>
<td>130-122-744</td>
<td>200-073-903</td>
</tr>
<tr>
<td>Transfer Set Coupler/Coupler</td>
<td>130-122-743</td>
<td>200-073-902</td>
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Category of change: Discontinuation of products

Current State: The Luer/Spike Interconnector and Transfer Set Coupler/Coupler are available as trade goods of Miltenyi Biotec, manufactured by MHMedical.

Planned change: Since the Luer/Spike Interconnector and Transfer Set Coupler/Coupler have been discontinued by MHMedical, the products will be discontinued on 30th June 2023 for the Asian/Pacific and Export markets. The discontinued products will be replaced by similar products of Miltenyi Biotec, developed and manufactured in-house. The design of the new products will be slightly changed:

For the Luer Spike Interconnector:
- White on-off clamp (instead of blue)
- Blue male Luer Lock cap for female Luer Lock (instead of white)

For the Transfer Set Coupler/Coupler:
- Non-vented spike white with cap (instead of vented spike with cap)
- Extension of the tube from 375mm to 800mm
- Replacement of roller clamp by white on-off clamp
- Introduction of blue tube guide, to neatly roll up the tube

Justification/Evaluation: Due to product discontinuation, the Luer/Spike Interconnector and Transfer Set Coupler/Coupler have to be replaced by internal, new products. The products were developed according to internal design processes. Slight adaptions were assessed to be non-critical as the raw material with direct contact to customer product is not changed. Tube extension of Transfer Set Coupler/Coupler leads to easier handling during operation.

The impact on the performance, quality and safety of the affected product was assessed to be low.

Estimated Implementation Q2/2023
Discontinuation of Luer/Spike Interconnector and Transfer Set Coupler/Coupler within the Asian/Pacific market

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

08. Oct. 2021
Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG