Implementation of a Unique Device Identification (UDI) code on TheraSorb® Adsorber labels

<table>
<thead>
<tr>
<th>Product</th>
<th>Material No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TheraSorb -Ig omni 1 Adsorber</td>
<td>330-000-793</td>
</tr>
<tr>
<td>TheraSorb -Ig omni 5 Adsorber</td>
<td>330-000-795</td>
</tr>
<tr>
<td>TheraSorb -Ig omni 1 Adsorber Kit</td>
<td>330-000-964</td>
</tr>
<tr>
<td>TheraSorb -Ig omni 5 Adsorber Kit</td>
<td>330-000-965</td>
</tr>
</tbody>
</table>

Category of change: Change of labelling

Current State: A label is placed on the above mentioned TheraSorb Adsorbers (product and carton label), and TheraSorb Adsorber Kits (kit label), including (but not limited to) REF number(s), LOT number and use-by date.

See example below:

![Figure 1: Example of current TheraSorb Adsorber Kit label](image_url)

Planned change: A UDI (Unique Device Identification) code will be placed on the product label, containing the following:

- [01] GTIN (Global Trade Item Number): 14 digits with company specific prefix 04049934
- [10] Lot number (up to 10 digits)
- [11] Production date: YYMMDD, if no expiration date is available
- [17] Expiration date: YYMMDD
- [21] Serial number (up to 8 digits)
- [91] Internal application and tracking number (optional).
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See example below:

![Example UDI on product label of TheraSorb Adsorber](image)

Figure 2: Example UDI on product label of TheraSorb Adsorber

**Justification/Evaluation:** Due to MDR requirements, a UDI code will be introduced for TheraSorb Adsorbers and TheraSorb Adsorber Kits.

There is no change of raw material or manufacturing process. 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.

p.p. 09-Jul-2021

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