Labeling on the device

Product:
MedDream

Product version: 8.3.0
Document version: 1.0
Date: 2023-10-26
Author: PM Raimundas Mikalauskas

Checked/ controlled/ evaluated by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>QM Laura Baroniené</td>
<td>2023-10-26</td>
<td></td>
</tr>
</tbody>
</table>

Approved by:

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not required</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Labeling on the device

Medical software MedDream does not have a tangible form. The only way to show information about manufacturer is to place this information in the „User Manual“ (as shown in Figure 1 “Information window” tab “ABOUT” and tab “REP”: annex No 1 to this document) and to make it visible by the software usage.

Information window tab “ABOUT” will display information mentioned below:

1. Full product name;
2. Version;
3. Release date;
4. UDI;
5. Medical device class;
6. ID of the notified body;
7. License to;
8. Concurrent connections;
9. Functions;
10. Valid to – empty if there is no termination in time;
11. Update to – date till the technical support and updates are provided;
13. Distributed by – Distributor contacts, if applicable (and distributor brand name, if applicable).

Information window tab “REP” is intended to display about authorized representative in different countries.
Annex No 1 to Labeling on the device: Information window tab „ABOUT“ and tab „REP“

Figure 1. Information window tab “ABOUT” and tab “REP”