
Labeling on the device

Product:

MedDream

Product version: **7.7.0**

Document version: **1.0**

Date: **2021-05-18**

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Checked/ controlled/ evaluated by:

Name	Date	Signature
QM Laura Baronienė	2021-05-18	

Approved by:

Name	Date	Signature
Not required		

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” as shown in annex No 1 to this document) and to make it visible by the software usage.

Information window 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. Modules;
10. Valid to – empty if there is no termination in time;
11. Update to – date till the technical support and updates are provided;
12. Manufactured by – Softneta UAB contacts.

Annex No 1 to Labeling on the device: Information window

ABOUT
Softneta

Product	MedDream
Version	7.7.0 Release notes (version is up to date)
Release Date	2021-05-18
UDI	(01)04779049590105(10)MDSY7700
Medical device class	Regulation (EU) 2017/745, Class IIb active medical device
ID of the notified body	0197
FDA Cleared	For diagnostic use K162011 (device class: 2)

License to	Softneta
Concurrent connections	Unlimited (Connected 4)
Functions	3D, Report
Valid to	2022-05-18
Update to	2022-05-18

FDA K162011
CLEARED

CE 0197

Manufactured by
Softneta, UAB
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Register **Close**

Figure 1. Information window.