Labeling on the device

Product:

MedDream

Product version: **8.8.0**

Document version: **1.0**

Date: **2025-12-05**

Author: **PO Raimundas Mikalauskas**

Checked/ controlled/ evaluated by:

Name	Date	Signature
QM Laura Baronienė	2025-12-05	

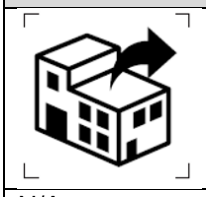
Approved by:

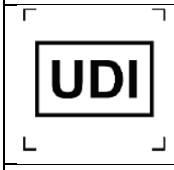
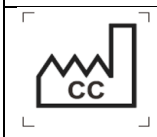
Name	Date	Signature
Not required	-	-

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” tab “ABOUT”, tab “REP” and tab “IMP”: annex No 1 to this document) and to make it visible by the software usage.

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

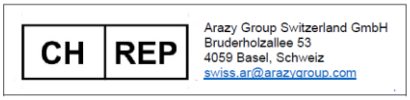
SYMBOLS USED*	REQUIRED GENERAL INFORMATION	VALUES	EXPLANATIONS (JUST FOR INFORMATION, NOT FOR INCLUSION IN “ABOUT” CONTENT)
	Distributed by	**See column “Explanations”**	Distributor contacts, if applicable (and distributor brand name, if applicable). MedDream UAB contacts, if distributor is not selected.
N/A	Address	**See column “Explanations”**	Distributor address, if applicable. MedDream UAB address, if distributor is not selected.
N/A	Contacts	**See column “Explanations”**	Distributor contacts (e-mail, webpage), if applicable. MedDream UAB contacts, if distributor is not selected.
N/A	License to	MedDream UAB	N/A
N/A	Concurrent connections	**See column “Explanations”**	Information on how many users (sessions) can be opened at the same time; in brackets - how many users (sessions) are actually logged in.
N/A	Functions	**See column “Explanations”**	Additional functionality that is activated in the installation depends on the purchase of a license
N/A	Valid to	**See column “Explanations”**	Empty if there is no termination in time.
N/A	Update to	**See column “Explanations”**	Date till the technical support and updates are provided (one year after the release).
N/A	Product	MedDream	Full product name
N/A	Intended use	MedDream is a software intended to aid in diagnosis by visualization various medical images, video and signals, measuring data in DICOM images and management DICOM images, when the patient is not in life-threatening state of health, time is not critical for medical decision and no major therapeutic interventions are required.	N/A
N/A	Version	**See column “Explanations”**	Version number, link to the release notes.

	Release date	**See column "Explanations"**	xxx-xx-xx (Year-Month-Day)
	Unique device identifier	**See column "Explanations"**	UDI
N/A	Catalogue number	MDSY	N/A
	Medical device class	Regulation (EU) 2017/745, Class IIb active medical device	N/A
N/A	ID of the notified body	0197	N/A
N/A	Certification registration No	HZ 2620158-1	N/A
N/A	FDA cleared	For diagnostic use including mammographic images K222320 (device class: 2)	N/A
N/A	Warning for USA	Mobile device display is intended for informational purposes only, not for diagnostic purposes.	N/A
		Warning, cautions and notes are described in User Manual, Instructions for use Operating requirements	In addition: link to the electronic instructions for use In addition: link to the Operating requirements
	Manufactured by	MedDream UAB, SRN: LT-MF-000011782	N/A
	Country of manufacture	Lithuania	N/A
N/A	Address	K. Petrausko st. 26, LT-44156, Kaunas, Lithuania	N/A
N/A	Contacts	info@meddream.com, https://www.meddream.com	N/A

*Used symbols in accordance with ISO 15223-1:2021 Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements).

Information window tab "REP" is intended to display about authorized representative in different countries as it is provided in the table below:

COUNTRY (JUST FOR INFORMATION, NOT FOR INCLUSION IN "REP" CONTENT)	**COUNTRY CODE (ALPHA-2 code)***	**INFORMATION ABOUT AUTHORIZED REPRESENTATIVES**	**ADDITIONAL INFORMATION REQUIRED**

United States of America	US	MEDES USA 601 Union Street, Suite 4200, Two Union Square, Seatle WA 98101, USA medes@arazygroup.com	Not required
United Kingdom of Great Britain	GB	MEDES LIMITED 5 Beaumont Gate, Shenley Hill, Radlett, Herffordshire WD7 7AR, England, UK medes@arazygroup.com	Not required
Switzerland	CH	Arazy Group Switzerland GmbH Bruderholzallee 53 4059 Basel, Schweiz	It is mandatory that the outer packaging of the product contains the name and the address of the Swiss AR adjacent to the CH-REP symbol: 
Singapore	SG	Mediezy Pte. Ltd 1 IRVING PLACE, THE COMMERZE@IRVING, #08-09, SINGAPOORE 369546 +65 6387 2430	Not required
Morocco	MA	DISTAMED 28 Rue Languedoc Quartier des Hopitaux 20360 Casablanca +212 5222-94615	Not required
Malaysia	MY	CVS Medical Sdn Bhd G-01-01, Plaza Kelana Jayla, Jalan SS7/13A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia +6037651082	Not required
Brazil	BR	Detentor do Registro no Brasil: Passrod Importação e Exportação de Produtos para Saúde Ltda - ME Rua José Jaime Delibo, nº 160 – Nova Aliança, Ribeirão Preto/SP, CEP: 14026-563 Tel: (16) 3421-8488	In accordance with Annex No 1 to the work instruction DI09-15 LABEL „Labeling“: „Labeling requirements in Brazil: labeling template“.
Thailand	TH	Imaging Connect Company Limited CPM Building, 3rd Floor , 976/10 Soi Sangjam, Bangkapi, Huai Khwang, Bangkok 10310, Thailand Tel. +66 88 089 0099	Not required
Serbia	RS	Magna Pharmacia d.o.o. Milutina Milankovića 7b 11 000 Beograd Serbia phone: +381 11 36 22 500 fax: +381 11 36 22 600	Not required.

Information window tab “IMP” is intended to display about authorized importers in different countries as it is provided in the table below:

COUNTRY (JUST FOR INFORMATION, NOT FOR INCLUSION IN “IMP” CONTENT)	COUNTRY CODE (ALPHA-2 code)*	INFORMATION ABOUT AUTHORIZED IMPORTERS	ADDITIONAL INFORMATION REQUIRED
Colombia	CO	ImpulMedicos S.A.S. con domicilio en Cra 45 (Autopista Norte) #147-66 Bogotá – Colombia Sanitary registration number: INVIMA 2025DM-0030738.	In Colombia, it is a regulatory requirements for medical device manufacturers to provide clear and accurate labelling for their product in Spanish. The labelling should encompass essential information such as the intended use of the device, detailed instructions for proper usage, important precautions, notable warnings and the manufacturer’s contact information. See Annex No 2 to this work instruction: „Labeling requirements in Colombia“

***Alpha-2 code is used** in accordance with ISO 3166 international standard “List of country codes by alpha-2, alpha-3 code”: free available in https://www.iban.com/country-codes

Information window TAB “BR” (Brazilia) template:

MedDream
MedDream UAB

Fabricante Legal:
MedDream UAB
K. Petrausko st. 26, LT-44156, Kaunas
Lithuania

Detentor do Registro no Brasil:
Passrod Importação e Exportação de
Produtos para Saúde Ltda - ME
Rua José Jaime Delibo, nº 160 – Nova
Aliança, Ribeirão Preto/SP, CEP: 14026-563
Tel: (16) 3421-8488

Registro ANVISA nº 81504790476
Data de Fabricação: DD / MM / AAAA
Lote: XXXXXX
Responsável Técnico: PAULO HENRIQUE PASSARINI **CREA-SP** 5069873360

Instrução de Uso/Condições Especiais de Armazenamento/ Conservação/ Manipulação/Advertências/ Precauções
“Ver Instruções de Uso”

Information window TAB “RS” (Serbia) data:

SYMBOLS / LABELS USED*	REQUIRED INFORMATION	VALUES (EXAMPLE)	NOTES / SOURCE
	**Proizvođač**	MedDream UAB, K. Baršausko 59, LT-51423 Kaunas, Litvanija	Manufacturer name and address
RS-REP	**Ovlašćeni predstavnik u Republici Srbiji**	[Naziv ovlašćenog predstavnika], [adresa], [e-mail, telefon] Magna Pharmacia d.o.o. Milutina Milankovića 7b 11 000 Beograd, Serbia phone: +381 11 36 22 500 jelena.vojinovic@magnapharmacia.rs	Must correspond to data registered in ALIMS
–	**Naziv i verzija softvera**	MedDream, verzija ……	Product identification
–	**Klasa medicinskog sredstva**	Klasa IIb (Pravilo 11)	As per Serbian classification rules
–	**Osnovni UDI-DI**	477904959MEDDREAMEE	When applicable
–	**Broj sertifikata o usaglašenosti EU**	HZ 2620158-1	If ALIMS recognizes EU certificate
–	**Sertifikat izdat od strane**	TÜV Rheinland LGA Products GmbH	Must match EC certificate
–	**Usklađenost sa propisima**	Uređaj je usklađen sa Zakonom o medicinskim sredstvima („Službeni glasnik RS“, br. 105/2017) i pratećim pravilnicima	Mandatory statement

Annex No 1 to Labeling on the device: Information window tab „ABOUT“, tab „REP“, tab “IMP”, tab “BR”, tab “RS”: