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MedDream

USER MANUAL

(version 8.9.1)

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General information

This user`s manual describes **MedDream** functionalities and operation with **MedDream**.
Seeking to ensure patient safety, software should be used by intended use. You should therefore ensure that you are thoroughly familiar with the user manual before setting up and using **MedDream** for the first time.
MedDream is dedicated only to show ePHI (Electronic protected health information) contained in study file. **MedDream** does not replace medical professionals and could be used only as an additional tool. No special facilities or special training of the medical software **MedDream** users are required.
Please note that medical images quality, sharpness, accuracy and other parameters, relevant to the users, directly depends on the technical capabilities of medical device, which is generating medical images, on the monitor and printer technical capabilities.
MedDream is a software – picture archiving and communication system – intended to display, process, read, report, communicate, distribute, store and archive medical data which are available as DICOM or/ and non-DICOM data, including mammographic images and bio signals. MedDream converts case related non-image documents, archives them as DICOM data and serves as a vendor neutral archive. MedDream supports the medical professionals in diagnosis.

INTENDED USE FOR ALL COUNTRIES EXCEPT UNITED STATES OF AMERICA
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. **Indications for 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. Contraindications: None. **Work environment:** The device is provided for the professional user. MedDream is intended for medical professionals and is provided to use in professional environments dedicated for medical diagnosis. Device is dedicated for continuous work.

INTENDED USE FOR UNITED STATES OF AMERICA
MedDream does not replace medical professionals and could be used only as an additional tool. No special facilities or special training of the medical software MedDream users are required. Please note that medical images quality, sharpness, accuracy and other parameters, relevant to the users, directly depends on the technical capabilities of medical device, which is generating medical images, on the monitor and printer technical capabilities. **Indications for Use:** MedDream is a software only Medical Image Management and Processing System intended to display, process, read, report, communicate, distribute, store, and archive medical data which is available as DICOM or HL 7 data, including mammographic images, and bio signals. MedDream also converts case-related non-image documents, archives them as DICOM data, and serves as avendor-neutrall archive. It supports the physician in diagnosis. Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants. **NOTE!** Web based image distribution on mobile device display of mammographic images are not intended for diagnostic purposes. **For users in the United States of America:** Mobile device display is not intended for diagnostic purposes.

WARNING! Mobile device display is intended for informational purposes only, not for diagnostic purposes.

WARNING! Software usage not by intended use may cause patient death, potential injury or serious health impairment, requiring professional medical intervention.

CAUTION! Consider country specific regulations regarding monitors and their maintenance.

⚠ **CAUTION**! In the U.S., for primary image diagnosis in Mammography only uncompressed or non-lossy compressed images must be used.

⚠ **NOTE!** This version is supported and validated for safe use until 2026-12-05; after that, safety and performance are not guaranteed.

Types of use: MedDream is intended for multiple patient multiple use.

MedDream Catalogue number: MDSY.

Known limitations:

- MedDream viewing functionalities may not be used with Internet Explorer 11 browser;
- MedDream viewing functionalities may be blocked by browser security if launched in iFrame.

Risk and Benefit: Using MedDream by its intended use does not cause risk, which could influence patient health status or health changes, but facilitate work of medical professionals, provide a better opportunity for accurate diagnosis.
Clinical data are collected, stored and managed as described below:

- By implementing post market clinical follow-up studies;
- By analyzing results of collected preclinical data;
- By implementing competitor analysis and literature analysis;
- By managing risk;
- By managing complaints and problems;
- By collection vigilance system data;
- By implementing biomedical research.

MedDream is continually tested. All critical issues are corrected immediately and users are informed about software functionality limitations and risks.
In case of MedDream bugs please immediately contact to MedDream support at this email: support@meddream.com.

Personal data security breach

In case of personal data breach (including but not limited to cybersecurity breach) please immediately (but not later than during 24 hours) inform medical software Manufacturer MedDream UAB by using below mentioned contacts: MEDDREAM Data Protection Officer (contacts of Data Protection Officer are public available www. meddream.com).
Name, Surname: Raimundas Mikalauskas
Tel. +370 630 06808
Mail: dpo@ meddream.com

Serious incidents reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (via email: support@meddream.com) and the competent authority of the Member State in which the user and/or patient is established (included but not limited to the Therapeutic Goods Administration (https://www.tga.gov.au/), as applicable).

Availability of documentation

The supported software versions are available on the MedDream UAB website (www.meddream.lt / www.meddream.com in the “Products” section) and electronic version of MedDream User Manual in supported language for the supported version is available on the MedDream documentation files site. User Manual could be opened in a browser or saved in pdf format and downloaded to Your computer.

CAUTION! Each version of the software is released with an updated User Manual. Please ensure that you are reading the User Manual that matches the version of the software you are currently using. Using the correct manual helps ensure the safe and proper use of the medical device in accordance with the applicable version.

Software Install Manual and Integration Manual are added as a separate document to the User Manual.
If You require paper version of User Manual, please ask us by email: support@meddream.com. Paper version of these documents will be sent not later than in 72 hours after receiving Your request (to the address You specify).

Questions

Please visit out F.A.Q. in MedDream UAB webpage for answers to frequently asked questions or problems.

WARNING! In the event of malfunction of the device or changes in its performance that may affect safety, contact to manufacturer.

CAUTION! Incorrectly installed software could cause inconvenience to medical professionals using the software and disruption of the medical professional activities.

If you have any questions or comments regarding MedDream functionalities or this user`s manual, please contact MedDream UAB Customer support: support@meddream.com.

Explanation of symbols used

During MedDream usage please pay attention to important information, related to patient safety, which is warning about software functions, whose implementation errors may pose a risk to patient health.
The symbols in this User Manual are intended to alert user about possible errors in the software or its use. Please read the information carefully as you see the symbols described below.

WARNING! This indicates a hazardous situation which may cause patient death, potential injury or serious health impairment, requiring professional medical intervention.

CAUTION! This indicates a hazardous situation which may cause minor potential injury, not requiring professional medical intervention, or simply cause inconvenience to medical professionals using software without affecting patient health status or health changes.

NOTE! Information, hints and advice for a better understanding of the instructions to be observed in the operation of the instrument.

Additional Symbols:

FDA CLEARED K222320 510(k) — FDA cleared product, which means the manufacturer can demonstrate that the product is substantially equivalent to another (similar) legally marketed device that already has FDA clearance or approval

CE 0197 — Product certified according to the Regulation (EU) 2017/745 by notified body TÜV Rheinland LGA Products GmbH

Country of manufacture

MD — Medical device

UDI	Unique device identifier
	Release date
	Distributor
CH REP	Contacts of representative in Switzerland
	Translation service provider information
	End user contacts
	Success message sign
	Info message sign
	Warning message sign
	Error message sign
	Tick box
	Search
	Search the full match
	Export
	Forward
	Upload
H	View icon
	Ascending/Descending
	System menu
	Grouped system tools
EN	Language menu
6	Notifications menu
	User details menu
	Patient history
	Get study changes
	Windowing
	Histogram
HU	Scale of histogram
	Synchronize windowing
	Invert
	Color palette selection
	Show DICOM overlay
	Zoom
	Fit to screen
1:1	Original resolution
	Zoom selection
	Fit to image
	Quadrant zoom
	Show quadrant layout
	Show quadrant location
	Pan
	Align Left
	Align Right
	Align Center
	Align & Lock Left
	Align & Lock Right
	Channels

Scroll; Series

Activate fast scroll between series

Show scrollbar

Magnifier

Digital Subtraction

Montage

Delete selected montage image

Save montage

Panels

Layout

Multi image/series

Reset

Export MPR to PACS

MPR (multi-planar reconstruction)

Show/Hide axes

Move axes to center

MPR layout with 3D image

MPR layout for three 2D image

Show 3D MPR image

Show 2D MPR image

3D image render quality

Change 3D image orientation
Anterior side

Posterior side

Left side

Right side

Inferior side

Superior side

3D image cropping

Change image order in MPR layout;

Switch to CPR view

Switch to 3D view

Curved planar reconstruction line

Show bigger image in MPR layout

Show smaller image in MPR layout

Spin

Auto Spin Forward or Backward

Reference line

Show for the first and last images in the series

Less strict reference line mode

Crosshair

Rotate

Rotate right

Rotate left

Flip horizontal

Flip vertical

DICOM

Link scrolled series

	Automatic link
	Manual link
	Distance link
	Sync actions
	Sync-zoom / Desync-zoom
	Measure
	Line, Ruler
	Polyline
	CPR polyline
	Angle
	Area
	Volume
	Cardiac volume
	Height Difference
	Ellipse
	Rectangle, 2D Bounding Box
	3D Bounding Box
	Circle
	Velocity Time Integral (VTI)
	Velocity
	Cobb Angle
	Tibial Plateau Angle
	Norberg Angle
	Vertebral Heart Scale

	Hip distraction index
	Tibial tuberosity advancement
	Cardiothoracic ratio
	Text
	Region of interest
	Myocardium ROI
	Repulsor; Myocardium ROI repulsor
	Spine Labeling
	Vertebra Angle
	Flexpoly
	Pencil
	Arrow
	Flatfoot
	Goniometry
	TT-TG Distance
	Time-Intensity Curve
	HTO angles
	Closed polygon
	Polygon
	Spline
	Point
	Add a new circle/ellipse ROI
	Add a new flex poly ROI
	Calibration line

	Show Angles
	Ruler
	Horizontal Line
	Continuous measurement
	Intensity
	Delete all or selected measurements
	Save presentation state
	Key objects
	Share files via DICOM Library
	Live share
	Copy live share link
	Info Labels
	Fusion
	Cine mode
Thum...	Thumbnails for mobile
CAD	CAD marks
CAD	CAD regions
	Mass mark
	Calcification mark
	Plugins
4D	4D tools
V	Construct 4D Series; virtual series thumbnail icon
	Show 4D slider
	Presenter tool
	Presenter tool. Fading line
	Presenter tool. Fading arrow
	Presenter tool. Draw
	Presenter tool. Laser pointer
	Whiteboard
	Swap
	Full Screen
	Theme
	Thumbnails
	Preload series
	Show/hide cardio phases
	Viewer studies list
	Patient details
	Print
HP	Hanging Protocol (HP)
	HP state saving enabled
	HP state saved
	HP state displayed
	Save workspace state
HP	Quick save HP
HP	Apply previous Hanging protocol
HP	Apply next Hanging Protocol
CP	Show next comparison study
	Measurement

	QT points
	HR
	QRS Axis
	Filter
25 -5mm/s +5mm/s	Change horizontal scale (mm per second)
10 -5mm/mV +5mm/mV	Change vertical scale (mm per mV)
	ECG view scrollbar
	Pause
	Play
	Previous Instance
	Next Instance
7.0	Frame rate in multi-frame
	Stop playback
	Multi-frame image playback synchronization modes
	Volume on
	Volume off
ALL	All, reported and not reported, studies
	Not reported study, Create report
	Reported study, Open/Edit report
	Paste to report
	Edit report template; Edit segment; Edit myocardium ROI;
	Delete report template, segment
	Download
	Burn disk
	Copy measurement; Copy a segment to another study
	Paste measurement
	Stop copy and paste measurement action
	Copy viewport content to the clipboard
	Copy original image to the clipboard
	Save viewport content as secondary capture DICOM
MIP	Generate Maximum Intensity Projection (MIP)
	Copy measurement values to clipboard
	Segmentation
	Segmentation. Segmentation tools tab
	Segmentation. Annotation tool tab
	Create Segmentation or Annotation
	Duplicate segment
	Locate segment
	Show/Hide segment
	Group / Ungroup by Series
	Change color
	Click to Edit; Select myocardium ROI
	Click to Send to Background
	Hover to Select
	Erase segment contour
	Contour
	Interpolation
	Paintbrush; Myocardium ROI Brush

	Paintbrush with Reference Pixel
	Fill Color
	Fill Paintbrush
	Smooth Edges
	Segment measurement
	Copy values to clipboard in CSV format
	Copy all segmentation measurements as CSV
	Undo last action
	Assign shortcut
	Minimize window
	Maximize window
	Restore window size
	Close window
	Help
	Use tool or item
	Pin tool or item
	Include tool or item in quick menu
Li Bi BS LW La	Interpolation types
	Range marking start and end action.
	DICOm Print
	DICOM Print. Load Active Series
ONCE	DICOM Print. Replace one image
ALL	DICOM Print. Reset all images
	Edit
	To start recording
	Take snapshot while recording
	Delete images or complete video
	Expand patient record
	Close study
	Open not saved (not converted to DICOM format) study in CURRENT STUDY window for more changes
	Open already saved (converted to DICOM format) study in DICOM VIEWER window
	Export the study to local or external drive
	Forward study to hospital DICOM archive
	New study in the list, not reviewed
	Study is not stored in hospital DICOM archive
	Study is stored in hospital DICOM archive
	Study and patient information are selected from scheduled modality worklist
	Try run task again
	Stop running task
	Rollback the task
	Delete task Delete source profile
	send DICOM C-ECHO and verify basic connectivity by DICOM protocol
	Activate source profile - display video input source streaming window in application include on startup
	Update or change source profile settings
	Reload all active sources

	Add new source profile		Add file
	Can copy full stream address		Add folder
	Download VLC media player format playlist file		Remove file
	Send to PACS functionalities		Expand to series level
			Notes and attachments

Summary of clinical evaluation report

The device's risks were managed according to MedDream UAB internal risk management work instruction, which is based on the ISO 14971:2019 standard. During the risk management activities, the device was:

- Classified according to the Regulation (EU) 2017/745 on medical devices Annex VIII as a CLASS IIb medical device (the device's risk management file);
- Identified according to the EU 2007/47/EC directive and requirements defined in the ISO 14971:2019 standard's Appendix C (the device's risk management file);
- Ensured risk managed (implemented risk analysis, risk mitigation actions, residual risks verification) (the device's risk management file);
- Tested and verified for residual risks (retested) according to the risk management results and MedDream UAB Testing work instruction (software tests, user acceptance tests, clinical tests), (the device's risk management file).
- All the risk management activities were carried out by the risk management team.

MedDream gathers production and post-production information using the following Quality management system's areas: product realization; measurement analysis and improvement; change and problem management; auditing; post market data results. The above-mentioned activities ensure, that internal and external environments (in which the product exists) are constantly monitored and if changes occur all associated risks are re-managed.
Residual risks (hazard) with the "minor" severity (Results in injury or impairment requiring professional medical intervention) are mentioned in the section „Warning regarding residual risks". We don't have any residual risk with "serious" (or higher) severity.
Calculated risk-benefit ratio (percentage) value is lower than 1 (one), therefore it is considered that the software benefit outweighs the risk that may be encountered while using the software.

List of applicable standards

Number	Requirements
EN ISO 13485:2016 + A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO / IEC 27001:2022	Information security, cybersecurity and privacy protection – Information security management systems - Requirements (ISO / IEC 27001:2022) ISO/IEC 27001:2022 – Information security management systems – Statement of Applicability (SoA) and Annex A control applicability.
ISO/ IEC 27005:2022	Information security, cybersecurity and privacy protection – Guidance on managing information security risks
EN ISO 14971:2019 + A11:2021	Medical devices – Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices – Guidance on the application of ISO 14971
IEC/TR 80002-1:2009	Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software
ISO 80001-1:2021	Application of risk management for IT-networks incorporating medical devices — Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software (used as informative only)
IEC/TR 80001-2-2:2012	Application of risk management for IT-networks incorporating medical devices – Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls
IEC 82304-1:2016	Health software – Part 1: General requirements for product safety
ISO 16142-1:2021	Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
EN 62366-1:2015 + AMD 1:2020	Medical devices - Application of usability engineering to medical devices – Amendment 1
ISO/IEC/IEEE 15026-1:2019	Systems and software engineering — Systems and software assurance — Part 1: Concepts and vocabulary
EN 62304:2006 +A1:2015	Medical device software - Software life-cycle processes CONSOLIDATED EDITION
IEC/TR 80002-3:2014	Medical device software — Part 3: Process reference model of medical device software life cycle processes (IEC 62304)
ISO/ IEC/IEEE 14764:2022	Software engineering – Software life cycle processes – Maintenance
IEC 81001-5-1:2021	Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
IEC/TR 80002-2:2017	Medical device software — Part 2: Validation of software for medical device quality systems
EN ISO 12052:2017	Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
ISO 11073-10101:2020	Health informatics — Device interoperability — Part 10101: Point-of-care medical device communication — Nomenclature (used as informative only)
AAMI HE75	Human Factors Engineering - Design Of Medical Devices. This recommended practice covers general human factors engineering (HFE) principles, specific HFE principles geared towards certain user-interface attributes, and special applications of HFE (e.g., connectors, controls, visual displays, automation, software–user interfaces, hand tools, workstations, mobile medical devices, home health care devices
ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
IEC 82079-1:2019	Preparation of information for use (instructions for use) of products
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols
ISO 7010:2019	Graphical symbols — Safety colors and safety signs — Registered safety signs
IEC/TR 62366-2:2016	Medical devices Part 2: Guidance on the application of usability engineering to medical devices
ISO 3166	List of country codes by alpha-2, alpha-3 code

IEC 81001-5-1:2021	Health software and health IT systems safety, effectiveness and security. Part 5-1: Security — Activities in the product life cycle
IEC TR 60601-4-5:2021	IEC Technical Report 60601-4-5 Medical electrical equipment - Part 4-5: Guidance and interpretation - Safety-related technical security specifications (used as informative cybersecurity reference)
2021/2226	Commission Implementing Regulation (EU) 2021/2226 on electronic instructions for use of medical devices.
207/2012 of 9 March 2012	Commission regulation on electronic instructions for use of medical devices
2017/745	Directive concerning medical devices Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2024/1860	REGULATION (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices
MDCG 2021-25	Application of MDR requirements to 'legacy devices' and devices placed on the market prior to 26 May 2021
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2019-11	Software: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR (EC)
MDCG 2022-16	Guidance on Authorised Representative Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)
MDCG 2019-7	PRRC. Guidance on Article 15 of the Medical Device Regulation (MDR) and in vitro Diagnostic Device Regulation (IVDR) regarding a 'person responsible for regulatory compliance' (PRRC) (EC)
MDCG 2021-5	MDCG 2021-5 Guidance on standardisation for medical devices (April 2021)
MDCG 2023-4	Medical Device Software (MDSW) – Hardware combinations. Guidance on MDSW intended to work in combination with hardware or hardware components
MDCG 2022-4, rev. 2 (May 2024)	Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD.
MDCG 2022-9 / Rev.1 (April 2024)	MDCG 2022-9 / Rev.1 Summary of safety and performance Template (April 2024)
MDCG 2020-8	Clinical Investigation and Evaluation: Post-market clinical follow-up (PMCF) Evaluation Report Template. A guide for manufacturers and notified bodies (EC)
MDCG 2020-7	Clinical Investigation and Evaluation: Post-market clinical follow-up (PMCF) Plan Template. A guide for manufacturers and notified bodies (EC)
MDCG 2025-10	Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices
MDCG 2020-10/1	Clinical Investigation and Evaluation: Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745 (EC)
MDCG 2020-10/2	Clinical Investigation and Evaluation: Clinical Investigation Summary Safety Report Form v1.0 (EC)
MDCG 2020-6	Clinical Investigation and Evaluation: Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies (EC)
MDCG 2020-1	Clinical Investigation and Evaluation: Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software (EC)
MDCG 2020-5	Clinical Investigation and Evaluation: Clinical Evaluation – Equivalence. A guide for manufacturers and notified bodies (EC)
SaMD WG/N41:2017	Software as a Medical Device (SaMD): Clinical Evaluation
MDCG 2019-9	Summary of safety and clinical performance
IMDRF MDCE WG/N56FINAL:2019 (IMDRF)	Clinical Investigation and Evaluation: Clinical Evaluation
IMDRF MDCE WG/N55 FINAL:2019 (IMDRF)	Clinical Investigation and Evaluation: Clinical Evidence
MDCG 2020-13	Clinical evaluation assessment report template
IMDRF MDCE WG/N57FINAL:2019 (IMDRF)	Clinical Investigation and Evaluation: Clinical Investigation
MDCG 2021-28	Substantial modification of clinical investigation under Medical Device Regulation

MDCG 2021-20	Instructions for generating CIV-ID for MDR Clinical Investigations
MDCG 2021-08	Clinical investigation application/ notification documents
MDCG 2021-6	Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation
2023/C 163/06	Commision Guidance on the content and structure of the summary of the clinical investigation report
MDCG 2018-7	MDCG 2018-7 Provisional considerations regarding language issues associated with the UDI database (Annex VI, Part A Section 2 and Part B of the Medical Device Regulation (EU) 2017/745 (MDR) and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR))
MDCG 2024-3	MDCG 2024-3 Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices (March 2024), including MDCG 2024-3 Appendix A: Clinical Investigation Plan Synopsis Template
MDCG 2024-5	MDCG 2024-5 Guidance on content of the Investigator's Brochure for clinical investigations of medical devices (April 2024), including Appendix A of the MDCG 2024-5.
IMDRF/GRRP WG/N52 FINAL:2019 (IMDRF)	Labelling: Principles of Labelling
MDCG 2021-26	Q&A on repackaging & relabelling activities under Article 16
IMDRF/UDI WG/N48 FINAL: 2019 (IMDRF)	UDI: UDI system
IMDRF/UDI WG/N7 FINAL:2013 (IMDRF)	UDI: UDI Guidance
MDCG 2019-1	MDCG guiding principles for issuing entities rules on basic UDI-DI
MDCG 2018-5	UDI: UDI Assignment to Medical Device Software (EC)
MDCG 2018-6	UDI: Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation 2017/745 and the In-Vitro Diagnostic Medical Devices Regulation 2017/746 (EC)
MDCG 2018-1 Rev.4 (2021 April)	Guidance on basic UDI-DI and changes to UDI-DI
MDCG 2022-7	Questions and Answers on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
MDCG 2021-10	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system
MDCG 2021-13 Rev.1	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
MDCG 2021-1 Rev.1	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
MDCG 2020-15	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
MDCG 2021-13 Rev 1	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers
MDCG 2019-5	Registration of legacy devices in EUDAMED
MDCG 2019-4	Timelines for registration of device data elements in EUDAMED
MDCG 2023-3	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices
MDCG 2022-21	Guidance on periodic safety update report (PSUR) accordig to regulation EU 2017/745 (MDR)
MEDDEV 2.12/1 Rev8	Report Form: Field Safety Corrective Action. Medical Devices Vigilance System
MEDDEV 2.12/1 Rev8	Report Form: Manufacturer's Incident Report. Medical Devices Vigilance System
MEDDEV 2.12/1 Rev8	Report Form: Manufacturer's Periodic Summary Report (PSR). Medical Devices Vigilance System
MEDDEV 2.12/1 Rev8	Report Form: Manufacturer's Trend Report. Medical Devices Vigilance System
MEDDEV 2.12/1 Rev8	MEDDEV 2.12-1 rev 8 on a medical devices vigilance system. Additional guidance on MEDDEV 2.12/1 rev 8 MEDDEV guidance documents (legacy). The MEDDEV 2.12/1 rev.8 vigilance guidance documents are legacy European guidance issued under Directives 93/42/EEC and 90/385/EEC. They are applied only where and to the extent permitted by Regulation (EU) 2017/745 (MDR), and only in the absence of or in support of applicable MDR Articles, Implementing Acts, or MDCG guidance, without overriding MDR requirements.

0.30.16-PROD	Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD) reporting template version 7.2. Device specific vigilance guidance. New MIR form.
MIR version 7.3.1 (SB-10449)	Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) Reporting Template Version: 7.3.1 (SB-10449) European Union Medical Devices Vigilance System APPLICABLE from 2025 November.
-	Template for a Field Safety Notice
GFTF/SG3/N99-10:2004 (Edition 2)	Quality Management Systems – Process Validation Guidance
August 2025	MDR Language requirements for manufacturers – Rev3 (August 2025)
MDCG 2019-16 rev.1	Guidance on Cybersecurity for medical devices
23 October 2024 **Applies from 11 December 2027**	Regulation (EU) 2024/2847 (Cyber Resilience Act – CRA) – horizontal cybersecurity requirements for products with digital elements (including software).
MDCG 2020-3 (rev.1, May 2023)	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
21 C.F.R. Part 801	U.S. FDA Medical Device Regulation: 21 C.F.R. Part 801 et seq. (Labeling)
21 C.F.R. Part 803	U.S. FDA Medical Device Regulation: 21 C.F.R. Part 803 (The Medical Device Reporting (MDR)
21 C.F.R. Part 806 Subchapter H	U.S. FDA Medical Device Regulation: 21 C.F.R. Part 806, Subchapter H (Report of Corrections and removals)
21 C.F.R. Part 807	U.S. FDA Medical Device Regulation: 21 C.F.R. Part 807 (establishment registration and device listing for manufacturers and initial importers of devices)
21 C.F.R. section 814.9.	U.S. FDA MAF Regulation: 21 C.F.R. section 814.9. (Medical Device Master File)
21 C.F.R. section 807 Subpart E.	U.S. FDA 510(k) Regulation: 21 C.F.R. section 807 Subpart E.
QMSR	U.S. FDA Quality Management System Regulation (QMSR). 21 CFR Part 820. Harmonized with ISO 13485:2016
21 C.F.R. Part 821	U.S. FDA Medical Device Regulation: 21 C.F.R. Part 821 (Medical device tracking requirements)
78 Fed. Reg. 58785, 58785-58828	UDI-GUDID Regulations: 78 Fed. Reg. 58785, 58785-58828 (Unique Device Identification System)
FDA	Overview of Regulatory Requirements: Medical Devices
FDA, June 14, 2023	Content of Premarket Submissions for Device Software Functions – Guidance for Industry and FDA Staff
FDA	General Principles of Software Validation; Final Guidance for Industry and FDA Staff
FDA	FDA guidelines to User Manual
2016/679	General Data Protection Regulation (GDPR; Regulation (EU) 2016/679
2022/2555	DIRECTIVE (EU) 2022/2555 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive)
IMDRF/CYBER WG/N60FINAL:2020 (IMDRF)	Cybersecurity: Principles and Practices for Medical Device Cybersecurity
FDA Food, Drug and Cosmetic Act (FD&C Act) Section 524B, as introduced by the Food and Drug Omnibus Reform Act of 2022 (FDORA)	U.S. FDA – Cybersecurity Requirements for Medical Devices Food, Drug and Cosmetic Act (FD&C Act) Section 524B, as introduced by the Food and Drug Omnibus Reform Act of 2022 (FDORA) Mandatory cybersecurity requirements for medical devices with cyber components, including premarket submissions (510(k), De Novo, PMA), secure design, vulnerability management, SBOM, and post-market cybersecurity monitoring
45 C. F. R. Part 160, subparts A and E of part 164	45 C.F.R. Part 160 (Public Welfare: The HIPAA Privacy Rule)
45 C. F. R. Part 160, subparts A and C of part 164	45 C.F.R. Part 160 (Public Welfare: The Security Rule)
Guidance on the provisions in the HIPAA Security Rule.1 (45 C.F.R. §§ 164.302 – 318.)	Guidance on Risk Analysis Requirements under the HIPAA Security Rule
-	Guidance on Cybersecurity for Networked Medical Devices Containing Off-the Shelf (OTS) Software
-	Postmarket Management of Cybersecurity in Medical Devices (Contains Nonbinding Recommendations)

-	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Guidance for Industry and Food and Drug Administration Staff
MDSAP Canada SOR/98-282	Medical devices Regulations SOR/98-282 (last amended 2025-05-31)
MDSAP Canada	Health Canada – List of Medical Devices – Notification of Shortages (incorporated by reference into SOR/98-282) and related obligations under sections 62.23–62.25 CMDR
MDSAP Brazil RESOLUTION - RDC N. 23	RESOLUTION – RDC N. 23, OF 04 APRIL, 2012 The situations in which are mandatory to registration holders of health product in Brazil to implement and report field actions, setting its minimum requirements
MDSAP Brazil RESOLUTION - RDC N. 67	RESOLUTION – RDC N. 67, OF 21 DECEMBER, 2009 General requirements for post-market surveillance
MDSAP Brazil RDC 665/2022	Brazilian Medical Device Good Manufacturing Practices (Resolution RDC 665/2022), 30 MARCH 2022.
MDSAP Brazil RDC 551/2021	Brazilian Field Actions (Resolution RDC 551/2021), 30 AUGUST, 2021
MDSAP Brazil RESOLUTION – RDC 751, OF SEPTEMBER 15, 2022, amended by RDC 777/2023 and RDC 810/2023 (and later amendments)	RESOLUTION – RDC 751, OF SEPTEMBER 15, 2022. risk classification, notification and registration schemes, and labeling requirements and instructions for the use of medical devices, amended by RDC 777/2023 and RDC 810/2023 (and later amendments)
MDSAP Australia	Therapeutic Goods (Medical Devices) Regulations, 2002 - consolidated version current as of 01-10-2025
UK SI 2005 No 1803	General Product Safety Regulations 2005 (SI 2005 No 1803)
UK MMD Act 2021 2002, (SI 2002 No 618)	Medicines and Medical Devices Act 2021 (MMD Act) UK Medical Devices Regulations 2002 (as amended post-Brexit) (SI 2002 No 618)
Switzerland MedDO, SR 812.213, 2023	Swiss Medical Devices Ordinance (MedDO, SR 812.213)
Morocco Law 84-12 and orders	Law 84-12 of Morocco The orders no. 2853.2854.2855.2856 relating to medical devices
Malaysia	Medical Device Act 2012 (Act 737) MDA/GD/0005 Guidance on the General medical device grouping. January 2024. Second Edition. MDA/GD/0007 Guidance on the Essential Principles of Safety and Performance of Medical Devices. March 2014. First Edition. MDA/GD/0013 Guidance on Field Corrective Action (FCA). June 2020 First Edition. MDA/GD/0020 – Guidance on Change Notification for Registered Medical Device. 21 November 2022. Fourth Edition. MDA/GD/0025 – Guidance on Declaration of Conformity (DOC). February 2016. First Edition. MDA/GD/0026 – Guidance on Requirements of Labelling for Medical Devices. February 2026. Seventh Edition.
Singapore Act 2007 (HPA)	Health Products Act 2007 (HPA)
Singapore Regulations 2010	Health Products (Medical Devices) Regulations 2010
Thailand B.E. 2551	Medical Device Act, B.E. 2551 (2008)
Colombia Resolution No. 1160	Resolution No. 1160 of 2016, which provides good manufacturing practice guidelines
Serbia	1. Закон о медицинским средствима (Zakon o medicinskim sredstvima) (Law on Medical Devices (the primary statute regulating medical devices in Serbia) Full text in Serbian via Paragraf: “Сл. гласник RS, бр. 105/2017” 2. Правилник о основним захтевима за медицинска средства (Rulebook on Basic / Essential Requirements for Medical Devices) 3. Правилник о регистрацији медицинског средства (Rulebook on Registration of Medical Devices) (“Службени гласник RS, бр. 84/2018”) 4. Правилник о обележавању и садржају упутства за употребу медицинског средства (Rulebook on Labelling and Content of Instructions for Use of Medical Devices) “Сл. гласник RS, бр. 4/2019”) Recently amendment / supplement (2024) to this rulebook: Pravilnik o dopunama Pravilnika o obeležavanju

	5. Правилник о vigilanci (Rulebook on Vigilance) “Сл. гласник RS, бр. 3/2019” 6. Правилник о промету на мало медицинских средстава у специјализованим продавницама (Rulebook on Retail Sale of Medical Devices (specialized stores)) “Сл. гласник RS, бр. 65/2018 i 98/2018” 7. Правилник о оглашавању лека, односно медицинског средства (Rulebook on Advertising of Medicines / Medical Devices) 8. Правилник о обавезама произвођача које се примењују на увознике, велепродаје и друга лица (Rulebook on Manufacturer / Importer / Distributor Obligations) 9. Правилник о производњи медицинских средстава (Rulebook on Manufacturing of Medical Devices) 10. Правилник о клиничком испитивању медицинског средства (Rulebook on Clinical Investigation / Clinical Trials of Medical Devices) 11. Правилник о промету на велико лекова и медицинских средстава (“Сл. гласник RS 69/2019”) (Wholesale trade conditions – applies to distributors) 12. Правилник о квалитету медицинских средстава (Draft rulebook aligning quality system requirements with MDR Art. 10(9))
Nr. XII-1938, suvestinė redakcija 2023-09-01	Biomedicininių tyrimų etikos įstatymas / Biomedical Research Ethics Law
Nr. V-4, suvestinė redakcija 2020-11-13	Įsakymas dėl prašymo išduoti leidimą atlikti biomedicininį tyrimą, paraiškos biomedicininiam tyrimui, biomedicininio tyrimo etinio vertinimo anketos pavyzdinių formų patvirtinimo / Order on the biomedical research forms approval: for of request for permission to implement biomedical research; biomedical research ethical evaluation form.
2017 m. gegužės 5 d. Nr. T1-683	Įsakymas dėl Valstybinės akreditavimo sveikatos priežiūros veiklai tarnybos prie Sveikatos apsaugos ministerijos generalinio direktoriaus 2004 m. rugpjūčio 5 d. įsakymo nr. T1-136 „Dėl pranešimų apie neatitinkančius reikalavimų medicinos prietaisus (budra) pateikimo tvarkos aprašo patvirtinimo“ pakeitimo / Order on the changes in vigilance system
Nr. T1-564, 2016-0412	Įsakymas „Dėl laisvos prekybos pažymėjimų išdavimo medicinos priemonėms (prietaisams) tvarkos aprašo patvirtinimo“ / Order “On Approval of the Description of the Procedure for Issuing Free Trade Certificates for Medical Devices”
Nr. T1-568, 2016-04-13	Dėl teikiamų rinkai medicinos prietaisų registravimo tvarkos aprašo patvirtinimo pakeitimo / Amendment of the approval of the description of the procedure for registration of medical devices placed on the market
2019-01-01 redakcija	LR asmens duomenų teisinės apsaugos įstatymas / Law on Legal Protection of Personal Data of the Republic of Lithuania
1T-63(1.12.E)	**Duomenų subjekto teisių įgyvendinimo pavyzdinės taisyklės.** *2018-07-09 Valstybinės duomenų apsaugos inspekcijos direktoriaus įsakymas Nr. 1T-63(1.12.E) /* Model rules for the exercise of the rights of the data subject. Order of the Director of the State Data Protection Inspectorate on July 9, 2018.
1T-68(1.12.E)	**Leidimų perduoti asmens duomenis į trečiąsias valstybes ar tarptautinėms organizacijoms išdavimo tvarkos aprašas.** *2018-07-18 Valstybinės duomenų apsaugos inspekcijos direktoriaus įsakymas Nr. 1T-68(1.12.E) /* Description of the procedure for the issuance of permits for the transfer of personal data to third countries or international organizations. Order of the Director of the State Data Protection Inspectorate, 2018-07-18.
1T-72(1.12.E)	Pranešimo apie asmens duomenų saugumo pažeidimą pateikimo Valstybinei duomenų apsaugos inspekcijai tvarkos aprašas. *2018-07-27 Valstybinės duomenų apsaugos inspekcijos direktoriaus įsakymas Nr. 1T-72(1.12.E). /* Description of the Procedure for Submitting a Report on the Infringement of Personal Data Security to the State Data Protection Inspectorate. July 27, 2018 Order of the Director of the State Data Protection Inspectorate.
1T-73(1.12.E)	Duomenų subjekto teisių gauti informaciją, susipažinti su asmens duomenimis, reikalauti ištaisyti ar ištrinti asmens duomenis ir apriboti jų tvarkymą įgyvendinimo, kai duomenų subjektas šias teises įgyvendina per Valstybinę duomenų apsaugos inspekciją, tvarkos aprašas. *2018-07-30 Valstybinės duomenų apsaugos inspekcijos direktoriaus įsakymas Nr. 1T-73(1.12.E) /* A description of the procedure for the data subject's right to receive information, access to personal data, request for the correction or deletion of personal data and the restriction of their processing when the data subject implements these rights through the State Data Protection Inspectorate. Order of the Director of the State Data Protection Inspectorate on July 30, 2018.
Serbia Сл. гласник RS 87/2018	Закон о заштити података о личности (“Сл. гласник RS 87/2018”) Law on Personal Data Protection – Serbian GDPR-equivalent (aligns with EU 2016/679 GDPR)

Serbia Сл. гласник RS 6/2016, 94/2017, 77/2019, 105/2021, 54/2023	Закон о информационој безбедности (“Сл. гласник RS 6/2016, 94/2017, 77/2019, 105/2021, 54/2023”) (Law on Information Security – national cybersecurity obligations; relevant to SaMD and connected devices)
Recast 2024	EU Product Liability Directive (Recast 2024)
Suvestinė redakcija po NIS2 perkėlimo, 2024 m.	Lietuvos Respublikos kibernetinio saugumo įstatymas (Law on Cybersecurity of the Republic of Lithuania)

Warnings regarding residual risks

No	Hazard	Warning/ Caution
1	Illegal access / Vulnerability of e-PHI (electronic personal health information)	**CAUTION!** Running MedDream software on shared user's account can lead to unauthorised access to patient's medical data. **CAUTION!** Incorrectly installed software could cause inconvenience to medical professionals using the software and disruption of the medical professional activities. **CAUTION!** Please notice, that closing the program without Log Off (using browser window close 'x' button) is not safe and may lead to unauthorized access to medical data. **CAUTION!** The system does not anonymize the content of shared images and entered message. You take responsibility for sensitive data in shared information. **CAUTION!** The system grants to the guests the access to all the studies, that are opened in host's Viewer window when starting live sharing, and these studies will be displayed in the thumbnail panel of the guests' Viewer window. Opening or closing the studies, while sharing is on, is not supported.
2	Inadequate filtration process	**CAUTION!** Be aware, that access to the storages may be restricted by the user rights. The storages list contains only the storages, that are granted for the user. Searching is performed only in the granted storages, if the **All storages** option is selected. **CAUTION!** Be aware, that access to the storages may be restricted by the user rights. If search for patient studies is configured in all storages, searching is performed in the storages, that are granted for the user
3	Incorrect configuration	**CAUTION!** Depending on application configuration, in case of corrupted frame the system may either show warning, or ignore the corrupted frame and show the last not corrupted frame instead. Contact your system administrator for system configuration. **CAUTION!** Do not activate multiple profiles for the same video input source. For e.g. added camera to profile A and the same camera to profile B and enabled both of them, to be active in VS application. In this situation, just profile A will start and profile B will fail, because input signal will be busy. It is possible to have A and B profiles active at the same time, if card allows this (for example, play input signal via windows direct show and other via capture card interface, if this exist). However, it does not make any sense to have 2 the same signals recording and it can cause unstable input stream recording process. **CAUTION!** The system shows warning before launching the import of the DICOM files from the external source, if the DICOMDIR file with the directory content is not present in the source media.
4	3rd party libraries / internal components work incorrectly / not available	**CAUTION!** PDF file is opened with default PDF reader. Some Web browsers have built-in readers. In other cases, the additional software for pdf reading and displaying, like Adobe Acrobat Reader, should be deployed in user workplace. **CAUTION!** On Windows OS it is recommended to have at least more than 2GB free space to function properly.
5	Component / function is missing	**CAUTION!** Export, and Forward functionality may be disabled. Contact the system administrator to verify the configuration, if export or forward is missing. **CAUTION!** Presentation state functionality may be disabled. Contact the system administrator to verify the configuration, if presentation state functionality is missing.
6	Software usage problem	**CAUTION**! In the U.S., for primary image diagnosis in Mammography only uncompressed or non-lossy compressed images must be used. **CAUTION!** Each version of the software is released with an updated User Manual. Please ensure that you are reading the User Manual that matches the version of the software you are currently using. Using the correct manual helps ensure the safe and proper use of the medical device in accordance with the applicable version. **WARNING!** In the event of malfunction of the device or changes in its performance that may affect safety, contact to manufacturer. **CAUTION!** The integrating hospital system may have and use different patient ID from different sources for the same patient. Be cautious and note that patient studies history from the particular source will not be accessible from the Viewer, if you do not initially open at least one study with each different patient ID. **CAUTION!** Note, that MedDream cannot guarantee that the manual series linking displays the images of the same patient and at the corresponding position. **CAUTION!** Until not saved, the created, deleted or edited segments are held in program temporary storage and will be lost, if closing the Viewer or closing the study, that has segmentations with unsaved changes.

No	Hazard	Warning/ Caution
		CAUTION! System tries to achieve the requested fps when playing multi-frame. If achieving the requested fps is not possible due to hardware or software limits, some frames may be skipped and not displayed to the user while playing. To see all frames, reduce the fps or use instance by instance navigation. **CAUTION!** The size limits for one attachment file and one-time upload package, that are defined in system configuration, cannot be exceeded. **WARNING!** Software usage not by intended use may cause patient death, potential injury or serious health impairment, requiring professional medical intervention. **WARNING!** Mobile device display is intended for informational purposes only, not for diagnostic purposes. **CAUTION!** Consider country-specific regulations regarding monitors and their maintenance. **CAUTION!** When connecting pedal and keyboard, review SNAPSHOT or PLAY/STOP KEY settings and try to avoid pressing configured keys. **CAUTION!** Please make sure Windows Firewall, Antivirus or other software do not block MedDream SendToPACS communication. It is recommended to turn off all blocking services in the Configuration and testing phase, to be sure that software will not be blocked. Also, it is important to make sure PACS server is not blocking DICOM communication by checking whether the communication is allowed in both sides – MedDream SendToPACS PC and Receiving PC.
7	Image display error or no display / display delay	**CAUTION!** Use the patient's name, dates, anatomical direction and other information, which is displayed in the viewport labels, to ensure that you are viewing the right image. **CAUTION!** Be cautious and ensure, that you are viewing the right place, if working with a zoomed image.
8	Measurements inaccurate	**WARNING!** MedDream cannot guarantee the accuracy of calibration data received from the modality. Note, that MedDream cannot guarantee that the manual calibration which is performed by users is done accurately. **WARNING!** The accuracy of the measurements is affected by the calibration status of the monitor. Monitor calibration ensures that tones that are lighter than black are displayed clearly separately from true black, and tones that are darker than white are clearly distinguished from true white. How to calibrate the monitors is described in the software installation instructions, which are provided separately in this user guide **WARNING!** Note, that measuring functions in MedDream is approximate. **WARNING!** When copying a segment to another study series, the copy operation may fail if the 3D coordinate systems between the studies are completely incompatible. **WARNING!** Copying a segment from one series to another may lead to shape distortion if the series have different distances between images or if they have different orientation parameters. The probability of this increases when the segment area is small. **WARNING!** If the localization of a segment does not fully overlap in another series, the segment will be clipped during copying to the next series, which may result in shape distortions.
9	Incorrect information: data is missing / corrupted / mixed / missread (including labeling data, if applicable)	**CAUTION!** Be cautious and verify the content before saving presentation state. All the measurements and text, including the zoomed outside of the currently viewed area, are saved and shared with other users viewing the study. **CAUTION!** Be aware that system automatically opens the presentation state after saving, as well as maintains the active measurement and text objects, that overlap with opened presentation state.

Short product description

MedDream is a HTML based package for PACS server which is designed to aid professionals in every day's decision-making process, connecting all the medical data into a unified and fast performing network. MedDream ensures a fast and reliable way to search, present and analyze the medical data (images and video files) on various devices: computers, smart phones, tablets and so forth. Intuitive user interface, simple, but very powerful software controllable by touchscreen Medical Panel PC. Storing locally more than 125 hours of HD videos and up to 100.000 of still images.
MedDream covers: radiology, cardiology, oncology, gastroenterology and many other fields of medical application. It seamlessly integrates with various medical imaging devices, such as: ultrasound (US), magnetic resonance (MRI), positron emission tomography (PET), computed tomography (CT), endoscopy (ES), mammography (MG), digital radiography (DR), computed radiography (CR), ophthalmology, and so forth.
Core MedDream uses are:

- Replacement of hard copies, e.g. film archives, paper documents, etc.
- Remote access. MedDream provides a possibility to be mobile and work from any place in the world where the Internet is accessible. More than one person can access and view medical records at one time. Such functionality speeds up the collaboration among the professionals. So, that a doctor in the hospital and a doctor that is in the different location may view the medical data and discuss about it simultaneously. The patient's medical history, various studies and images are found much faster comparing to the conventional paper-based methods.
- Multiplanar and 3D reconstruction from series of images 3D perspective together with views in reconstructed planes enables viewing the region of interest from several perspectives, and allows more accurate and faster diagnostic.
- MedDream can be used as a standalone WEB Viewer or integrated into PacsOne PACS, dcm4chee Archive, Conquest PACS, ClearCanvas PACS systems. Moreover, MedDream can be adapted to client's PACS system and easily integrated into RIS/HIS workflow.
- MedDream has multiple functions such as search of studies, viewing, analyzing, saving, exporting, forwarding images and videos, etc.
- High-quality video recording into DICOM by using MPEG2 and MPEG-4 AVC/H.264 compression.
- Record/take multiple low and high (full HD) quality video/snapshots during the surgery or other procedures.
- Live stream video during the procedure.
- Record, stream, play video and take snapshots at the same time.
- Record video/take images from multiple connected devices (special video card needed).
- Flexible patient data assignment: selecting already existing patient, manually entering the patient details or selecting from hospital DICOM worklist server.
- Possibility to start a new study recording, while other video/snapshots is in progress for saving to DICOM or sending to DICOM archive.
- Review medical images/video during the surgery or other procedures.
- Trim the recorded video.
- Recorded studies can be stored locally, sent to the hospital DICOM archive (PACS) or exported to other storage devices.
- View saved images/videos with integrated DICOM Viewer.
- Image to DICOM feature. Convert BMP, PNG, TIF, JPG images and send to PACS.
- Video to DICOM feature. Convert AVI, MPG, MPEG, WMV, MOV, MP4, H264, MKV, FLV video files and send to PACS.
- Possibility to update patient information in DICOM files before sending to PACS.
- Possibility to add additional information field (additional custom DICOM tag) to image.

- Possibility to configure only Worklist usage for Non-DICOM studies.
- Possibility to configure Institution name (tag (0008,0080)) and Station name (tag (0008,1010)) and use it in DICOM files.
- Possibility to set files filter (set custom file extension in application.properties file).
- Detailed information about files to be converted: image preview, image info view, DICOM info and DICOM tags view, DICOM pixel data extraction.
- Archive file's support. Automatically extract archive: ZIP. Supports 7z, ISO archives, but requires install 7-Zip software.
- Automatic DICOM files recognition (exclude DICOMDIR and unknown files).
- Supported patient information: patient ID, full patient name (alphabetic, ideographic and phonetic), birthdate and sex.
- Supported study information: study UID, study ID, date, time, accession number, description, series number, modality and character set.
- Possibility to specify character encoding: supported all extended character sets defined in the DICOM standard.
- Allows append existing study with new files (select study and patient information from scanned DICOM files).
- Supports Modality Worklist Information (C-FIND), Query/Retrieve Information, Verification (Echo).
- Support Drag and Drop interface.
- Querying patient information from HIS using external API (HTTP request).
- Possibility to initiate actions from other app by using REST API: Modality Worklist search, non-DICOM convert to DICOM, send to PACS.
- Windows explorer context menu (right mouse button) support.
- File conversion and forward process logs.
- Supporting Enterprise license.

Features of MedDream software:

- Multi language support (EN, LT, DE, ES, IT, FR);
- System administration via WEB interface;
- User identification by username and password, user rights;
- Ability to save image viewing settings;
- Secure data transfer (SSL support);
- Ability to open more than one study at a time;
- Image transformation (rotate, flip, align, pan, scale)
- Image inversion;
- Intensity (density of the point) measurement;
- Changing the Level/Window values;
- Measurements: Line, Reference line, Angle, Area, Volume, Cobb angle, Velocity time integral (VTI), Heart cardiothoracic ratio (CTR);
- Tools for localization of the images in intersecting planes;

- Multiplanar reconstruction (MPR);
- Additional data for image support (presentation state and key object);
- ECG support (Tools: Beats per minute (bpm), time (s), millivolts (mV), QT points, heart rate (HR), QRS axis);
- Reports for study;
- Hanging protocols.

Product customization

Customizing the MedDream software allows providing the required set of functionalities to the system user:

- MedDream Viewing functionalities;
- MedDream Video viewing and converting functionalities;
- MedDream PACS functionalities;
- MedDream SendToPACS functionalities.

System appearance, and availability of tools may be also customized by changing the settings. See the detail functionalities description and description of Settings in annexes of this document. The detail MedDream PACS functionalities description see in MedDream Configuration Manual of MedDream PACS functionalities.

Product labeling

The information about the product is provided to the system user in the About window:

- Contacts of product distributor.
- Licensing information: organization that owns the license of current product installation, and dates, until the current license is valid and will receive updates.
- Product information: product name, product version, release date.
- Unique Device Identifier.
- Certification information: Catalogue number, Medical device class, ID of the notified body, Certificate registration number, and FDA cleared mark.
- Contacts of product manufacturer.
- Warning regarding not using mobile display for diagnostic of mammographic images.
- Explanation of safety signs with references to Instructions for use and Operating requirements.
- Certification bodies designated agents contacts are available in REP (representatives) tab.
- Importers contacts are available in IMP (importers) tab.
- Contacts for Brazil are available in BR tab.
- Contacts for Serbia are available in RS tab.

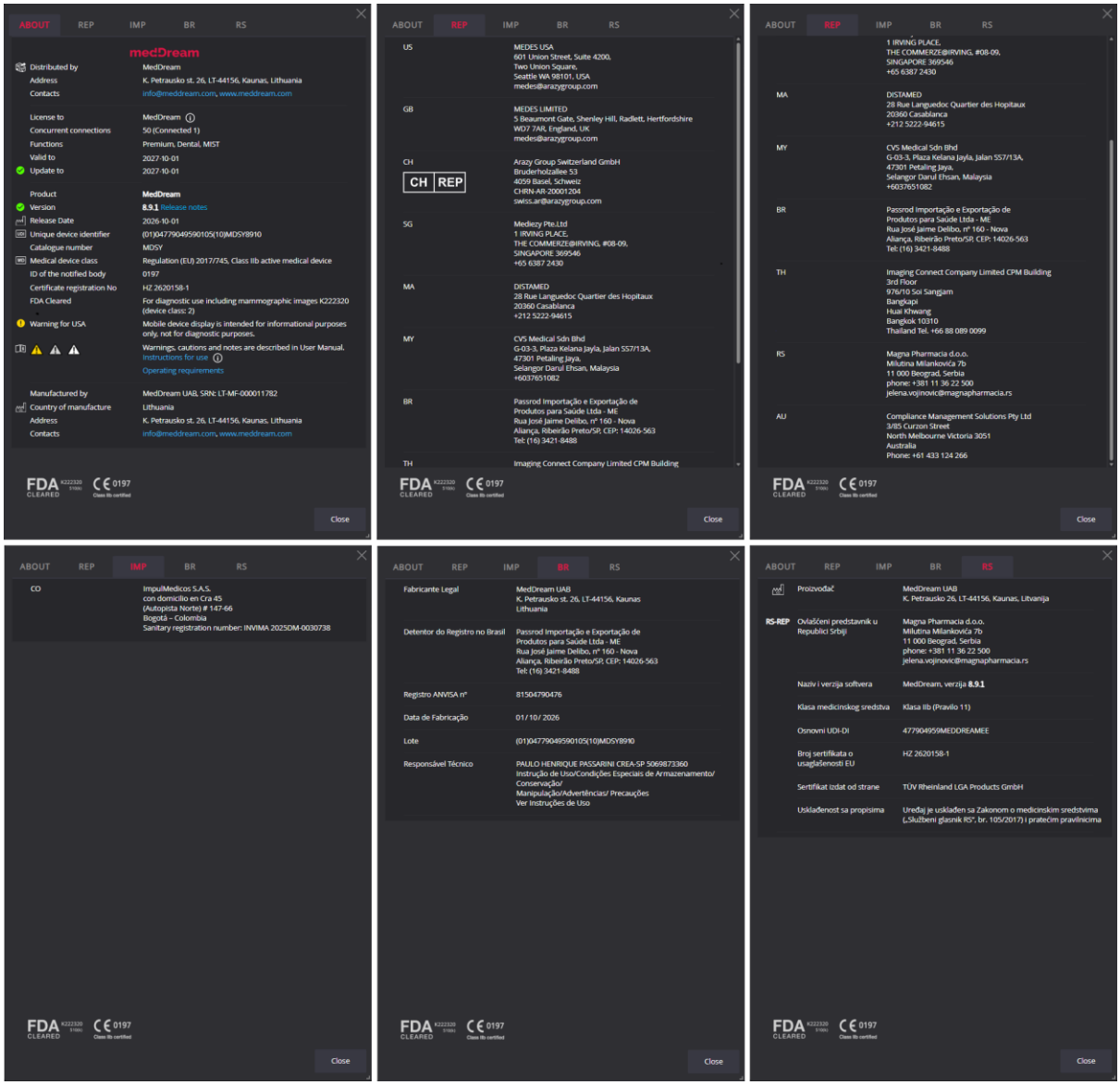

Figure 1 Product labeling

See the detail description of About window (excluding table "REP", which is presented only in GENERAL part of User Manual) and how to access it in annex of the particular functionalities.

License agreement and registration

⚠ **NOTE!** License registration is required for legal software use.
The access to the Software License Agreement (EULA) and license registration is provided to the end user in the system. To register the license or license update, the user should do the following:

- apply for the license and receive the valid license number from system administrator or system provider,
- read the Software License Agreement and agree with it,
- enter the license information and register license.

See the detail description of license registration steps in annexes of this document.

⚠ **NOTE!** The internet connection and access to license server should be ensured for successful license registration.

Access to user documentation

The user manual user is available in MedDream under the Help menu. See the detail description how to access Help menu in annexes of this document.

Product installation

MedDream viewing functionalities minimal hardware requirements

Server-side

MedDream software is intended to be installed on PCs, servers or other hardware systems. Minimal hardware requirements as well as OS and other supporting software requirements for MedDream viewing functionalities are listed below:

Parameter	Minimal Requirements
CPU*	Intel® Core™ i5, 4 Core, 2.00 GHz
RAM	8+ GB Additional RAM memory must be reserved for OS, Database, PACS and/or other services if installed in the same machine.
Storage space	1 GB of available hard-disk space for installation; + minimum 2 days of accessible study amount. For better performance preparation cache service can be used: additional free space required for local archive and image caching (see cache management description). Storage disk performance (used for caching) directly affects image open speed (SDD, RAM or HI speed disk storage recommended).
Network Bandwidth	100+ Mbit/s
Operating system	Windows Server 2019, Windows Server 2022, Windows Server 2025 Windows 10, Windows 11 (64 bit only) and above, Debian 13, Ubuntu 26.04 LTS, Ubuntu 24.04 LTS, Fedora 44

*Minimal hardware requirements depend on number of concurrent users:

Concurrent Connections	CPU cores	RAM
1 connection	4 cores	8 GB
2 connections	4 cores	8 GB
5 connections	4 cores	8 GB
10 connections	4 cores	12 GB
20 connections	6 cores	16 GB
30 connections	8 cores	32 GB
60 connections	16 cores	32 GB
60+ connections	+1 core per 10 connections	+1 GB per 5 connections

⚠ **NOTE!** Minimal hardware requirements depend on number of concurrent users, workload and image types. It is recommended to allocate 20-80% more resources for unusual work load or specific data types.

The requirements for MedDream server, detail instructions, how to install MedDream and verify the MedDream functioning after system installation or restart, are provided in Install Manual.
Current section provides the requirements for user workplace and instructions for verifying, that the user can access MedDream functionalities from his workplace.

Client-side

The table describes the requirements for computer, that uses MedDream viewing functionalities from remote MedDream server through the internet:

Parameter	Minimal Requirements
Desktop Web	
CPU	Intel® Core™ i3 4 core CPU or better

RAM*	8+ GB, 256+ MB of video memory
Storage space	10+ GB
Network Bandwidth	100+ Mbit/s
Web Browsers	Chrome 148+, Firefox 151+, Microsoft Edge 148+, Safari 26+
Mobile device iOS Web	
RAM*	2+ GB
Storage space	2+ GB
Network Bandwidth	100+ Mbit/s
Web Browsers	Safari 26+, Chrome 148+
Mobile device Android Web	
RAM*	2+ GB
Storage space	2+ GB
Network Bandwidth	100+ Mbit/s
Web Browsers	Chrome 148+, Firefox 151+

* For CT, MRI, PET-CT client side MPR/MIP rendering:
- 64bit CPU and 64bit operating system;
- Graphic board with >=1 GB video memory (hardware acceleration is enabled on the browser);
- 12 GB of RAM to open more than 800 images;
- 16 GB of RAM to open more than 1500 images;
- 24 GB of RAM to open more than 3000 images (cardiac or functional imaging, MG Tomosynthesis).

* For MG Mammography:
- 64bit CPU and 64bit operating system;
- Graphic board with >=1 GB video memory (hardware acceleration is enabled on the browser);
- 16 GB of RAM.

* For MG Tomosynthesis:
- 64bit CPU and 64bit operating system;
- Graphic board with >=1 GB video memory (hardware acceleration is enabled on the browser);
- 16 GB of RAM.

* Depending on the total amount of RAM on user's workstation, the browser is allowed to allocate the restricted amount of memory, and therefore MedDream application may load not more than 16 GBytes of data. Due to these limitations, browser may run out of memory, if the user loads several large computed tomography, mammography or tomosynthesis studies.

⚠ **NOTE!** Hardware acceleration should be enabled in web browser for better performance.

⚠ **NOTE!** Mozilla Firefox browser has certain memory limitations: MIST MPR functionality will fail on series where uncompressed DICOM data is larger than 2 GB.

⚠ **NOTE!** MedDream enables users to view all data stored with a bit depth of up to 16 bits per color channel. However, it displays 8 bits per color channel at a time due to web browser limitations (maximum display of 256 values per color channel). You can utilize the Window leveling tool to explore the entire data range within the images.

⚠ **NOTE!** The MedDream viewing functionalities server system requirements are detailed in the Install Manual of the MedDream viewing functionalities.

Minimal MedDream video viewing and converting functionalities hardware requirements

The table describes the requirements for computer with locally installed MedDream video viewing and converting functionalities:

Parameter	Minimal Requirements
CPU	Intel® Core™ i5 or i7 When using FHD streaming, recording and playing at the same time:

	4 threads, 4 GHz or 8 threads, 1.8 GHZ.
RAM	8+ GB
Storage space	Storage disk 500 GB (Storage disk speed directly affects application performance) depends on usage workflow, can be >=256 GB, ~7 days requires 56 GB
Network Bandwidth	100+ Mbit/s
Operating system	Windows 10, Windows 11
Screen resolution	1920x1080 pixels (lower resolution not supported)

⚠ **NOTE!** We recommend upgrade PC or reduce video quality, if it does no match minimal requirements for recording, playing and streaming at the same time.
If you faced with such a problem, please contact MedDream UAB Customer support – e-mail support@meddream.com and we will help you resolve it.

Minimal SendToPACS functionalities hardware requirements

The table describes the requirements for computer with locally installed SendToPACS functionalities:

Parameter	Requirements
CPU	1 GHz or faster with support for PAE, NX, and SSE2
RAM	1+ GB
Storage space	1+ GB
Operating system	Windows 10, Windows 11

Minimal PACS functionalities hardware requirements

Server-side

Parameter	Requirements
CPU	Intel® Core™ i5, 4 Core, 2.00 GHz
RAM	8+ GB
Storage space	• 20 GB available hard-disk space for installation; • PACS storage calculator for data: https://dicomlibrary.com/dicom/pacs-storage-calculator/ • 0.5 % from calculated storage data for DB storage.
Network Bandwidth	100+ Mbit/s
Operating system	Windows Server 2022 Windows 11 Debian 13, Ubuntu 24.04 LTS, Fedora 43
Database	MySQL Server 8.0

Client-side

The same requirements as MedDream Viewer functionality (excluding mobile).

Installation verification

After installing the software or upgrading the version, the administrator must check against the Verification Checklist defined in the install manual.
The section below provides short check list for verifying, that the user can access MedDream functionalities from his workplace, view studies and use MedDream tools, required for daily operations.
Users who do not have administrator rights (e.g. doctors, nurses, technicians, etc.) must monitor the notifications and warnings provided by the system and inform the system administrator about them.
In the event of an increase in system notifications, the system administrator must review the system logs and re-evaluate the performance of the system against the Verification Checklist defined in the installation manual.

MedDream viewing functionalities

To verify the MedDream viewing functionalities, perform the following steps:

- Open study in MedDream.
- Use your usual way to connect to MedDream service and open the MedDream Viewing functionalities: execute the known valid study open URL, or login with your credentials and select the study in MedDream search window.
- If you usually are working with studies from several network storages, try opening studies from all the used network places.
- Check that study is correctly opened: thumbnails are displayed instead of exclamation marks, the chosen images open as well.
- Check the Viewer toolbar for the opened image: make sure, that you usually used tools are displayed in common place and accessible.
- Verify the working of functions and tools, that are critical to you daily operations (like measuring, patient history, zoom, pan).

MedDream Video viewing functionalities

To verify the MedDream Video viewing and converting functionalities, perform the following steps:

- Use your usual way to connect to MedDream and open MedDream Video viewing functionalities: execute the app, video source should be connected to PC;
- Check the video signal in view window. If no signal is displayed, try to refresh signal, otherwise check the chapter „Recording settings“ in Annex II MedDream video viewing and converting functionalities;
- Try to create a new patient, or Try to select patient from worklist – if worklist is available, check configuration chapter „Selecting patient from DICOM modality worklist“ in Annex II MedDream video viewing and converting functionalities;
- After patient is created or selected from worklist try to record video. If having problem, check chapter „Recording settings“ in Annex II MedDream video viewing and converting functionalities, otherwise contact system administrator or support@meddream.com

MedDream PACS functionalities

To verify the MedDream PACS functionalities, perform the following steps:

- Use your usual way to connect to MedDream service and open the MedDream PACS functionalities.
- Find the study in the way you’re regularly using:
  - Use unread studies page;

  - Browse the patients list and open the patient's studies list;
  - Open search page, enter search criteria and find the study.
- Open the series page for the selected study.
- Check if you are able to perform functions, you're regularly using. The functions to think about:
  - Export studies;
  - Import studies;
  - Modify studies content.

MedDream SentToPacs functionalities

To verify MedDream SentToPACS functionalities, perform the following steps:

- Test non-DICOM file image converting and sending workflow:
  - Add one or more files to the files list. Use all the file types you regularly are working with;
  - Enter the DICOM info for non-DICOM files;
  - Select DICOM device;
  - Initiate converting and sending;
  - Check, that files are converted to DICOM and sent to the device, using the MedDream PACS functionalities or MedDream viewing functionalities.
- Repeat the non-DICOM file image sending workflow with all the DICOM devices you are regularly using.
- Test patient search in the Worklist workflow, if you are using these functions:
  - Select search in the non-DICOM files info window,
  - Enter or modify the search criteria to search specific patient. For testing purpose, use least specific criteria to see all patients available, like check ALL Modalities checkbox, uncheck Date checkbox, or search only by date;
  - select Worklist device from drop down list;
  - Press "Search" button to search in the Worklist server database;
  - Select the patient from the results list, and press "OK" to close Patient Search window. Check, if the selected patient`s data is inserted into corresponding Patient and Study information fields of the NON-DICOM files info window.
- Repeat the patient search in the Worklist workflow with all the Worklist devices you are regularly using.

IT security measures

The "Security considerations" section in the Install Manuals of the particular MedDream functionalities provides detail recommendations, how to install and configure the MedDream Viewing functionalities, MedDream Video viewing and converting functionalities, MedDream PACS functionalities, and MedDream SendToPACS functionalities in order to ensure the system security.
Current section describes actions, that should be taken by MedDream user, in order to secure his workplace and user's account against unauthorized access:

- It is highly recommended to run MedDream only from the devices and accounts, that are authorized for the user by company's security policy. Company's security policy should ensure:
  - that work network and user's workplace is secure – servers and workplaces (computers, mobile devices) have latest OS version with latest security patches,

- that user's workplace is free of viruses - required antivirus software is installed and run regularly,
- that no extra peripheral devices are connected to the user's workspace except the necessary for work,
- that company's network is protected with firewalls (Wi-Fi with strong passwords, limited access protocols) and other protection means,
- all portable devices used for work (tablets, phones, notebooks) should be with strong passwords, encrypted storage and able to connected only to work environment thru secure network,
- portable Devices must be physically locked or otherwise appropriately secured by its user/custodian when left unattended.

⚠ **NOTE!** Browser cache is not encrypted by default, which may expose sensitive data. To protect sensitive information indirectly, it is recommended to:
1) Enable full disk encryption on the system.
2) Regularly clear your browser cache.
3) Avoid using public OS accounts or devices (e.g., shared PCs).
4) Use secure browser profiles or private browsing modes when handling sensitive data.

⚠ **CAUTION!** Running MedDream software on shared user's account can lead to unauthorized access to patient's medical data.

- It is recommended to use the browser, that is authorized according company's security policy, and is compatible with MedDream software:
  - If company's security policy does not give recommendation for browser, we would recommend considering the Google Chrome or Mozilla Firefox as the most secure browser alternatives in the market at the moment while is up to date with latest security patches.
  - Browser should be configured to clear all data when closed, to prevent the data leak from work space data traces.
- The authentication is required for MedDream software. However, the authentication ways may vary. If you are using login and password authentication, keep the password safe from unauthorized access:
  - (if mobile devices used at work tool) before entering URL check that device connected to secure and exactly that network which was provided by system administrators;
  - before entering user name and password, check that URL address is correct and secure (https);
  - before entering user name and password, check the network connected;
  - don't use short and simple passwords (12-16 symbols minimum). If system administrator didn't give you secure password, ask for it;
  - do not expose the password to other persons;
  - do not allow the browser to save the password;
  - if you forgot your password, got the wrong password messages, or there is a chance that password can be compromised, stolen or publicly accessible, contact your system administrator to change the password as soon as possible.
- Use MedDream shutdown function, after finishing your work.
- Use MedDream log off function, after finishing your work and before closing browser window. Closing the program without Log Off (using browser window close 'x' button) is not safe and may lead to unauthorized access to medical data. It is recommended after log out of MedDream to close browser completely, not only tab, but all browser window in order to clear browser data in memory.

⚠ **NOTE!** Note for user, that share the computer and user's account. MedDream is designed with "zero footprint" concept, meaning that no patient data is left on a client machine: after the end user logs out from MedDream, its cache does not contain any server responses with patient data. However, there are known browser's security bugs, that allows to extract potentially sensitive data from browser's memory cache after the user logs out and doesn't

close the entire browser application. Therefore, it is recommended to also close the entire browser (not just a particular tab or one of the windows) after logout.

- Contact your system administrator as soon as possible in case of unusual, malicious and suspicious behavior of software:
  - if there are any suspicions that work station can be compromised (computer miss behaving, have malware or popping random windows out of nowhere, being slower than usually), accessed by unknown person directly/remotely or stolen;
  - if there is network with similar name or devices connecting to wrong network;
  - if connection to MedDream looks insecure or address mismatch the one, that was given to you by your system administrator;
  - if some strange text messages, studies or links started to appear in MedDream viewer, buttons and shortcuts opens suspicious pages;
  - if MedDream viewer not opens, returns errors like "Page not found" or "Unable to connect", or loading time increased significantly;
  - if downloaded study files being alerted as infected or viruses. Files, downloaded from MedDream export functionality, can be checked with VirusTotal. Contact your system administrator if you need to install or update the VirusTotal software, which can be obtained from https://www.virustotal.com/;
  - if portable work devices (phones, tablets, laptops) were stolen;
  - if portable work devices (phones, tablets, laptops) left unattended and have chance that devices security can be breached.
- In case of loss of the mobile device, the administrator must be informed immediately in order to completely remove the user's access to patient data and prevent them from being made public.

MedDream functionalities: list of annexes

The section provides list of annexes, that describe in details usage and configuration of MedDream functionalities.

- Annex I: MedDream viewing functionalities;
- Annex II: MedDream video viewing and converting functionalities;
- Annex III: MedDream SendToPACS functionalities.

See each annex in a separate document.

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Authorized representatives / importers and statements due to compliance

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Serbia	Magna Pharmacia d.o.o. Milutina Milankovića 7b 11 000 Beograd Serbia phone: +381 11 36 22 500 fax: +381 11 36 22 600	Ovaj softver je medicinsko sredstvo i u potpunosti je usklađen sa zahtevima Zakona o medicinskim sredstvima Republike Srbije / This software is a medical device and fully complies with the requirements of the Law on Medical Devices of the Republic of Serbia. See: MedDream as IIb class
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	Bogotá – Colombia Sanitary registration number: INVIMA 2025DM-0030738	See: INVIMA RESOLUTION No. 2025027751
EU	N/A	This software is a medical device and is in conformity with the medical device legislation of European Union (MDR) and is certified as IIb class medical device by TÜV Rheinland LGA Products GmbH (0197). See: certified as IIB class medical device according the MDR.
Canada	N/A	This software is a medical device and is in conformity with the medical device legislation of Canada and is registered by the Authority of Canada (Health Canada). See: Medical device license No. 112910.

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MedDream is manufactured by MedDream UAB.
Medical device class: Regulation (EU) 2017/745
Class IIb medical device
FDA cleared K222320
ID of the notified body: 0197
Document version 1.0
Date of issue: 2026-10-01
Language: EN

CE 0197
Class IIb certified

FDA K222320 510(k)
CLEARED

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