

Medical Device Labeling Requirements

Comprehensive regulatory labeling requirements for medical devices in Croatia, based on EU MDR 2017/745 and national HALMED requirements.

COUNTRY
Croatia 🇧🇪

PRODUCT TYPE
Medical Devices

FRAMEWORK
EU MDR 2017/745

COMPETENT AUTHORITY
HALMED

REPORT DATE
May 2026

REPORT VERSION
V.1

COUNTRY OVERVIEW

REGULATORY FRAMEWORK

EU MDR 2017/745 (directly applicable) + Medical Devices Act (OG 76/13) + National Ordinance (OG 84/13, 126/19, 32/21)

EU MEMBER STATE

Yes — EU Member since 2013. CE marking is the primary market access mechanism. EUDAMED registration applicable.

COMPETENT AUTHORITY

HALMED — Agency for Medicinal Products and Medical Devices of Croatia (Agencija za lijekove i medicinske proizvode)

NATIONAL NOTIFICATION

Class IIa, IIb, III devices and IVDs must be notified to HALMED within 15 days of market placement (waived if EUDAMED-registered with Croatia listed).

Important: Croatia, as an EU Member State, directly applies EU MDR 2017/745 (Regulation (EU) 2017/745). Labeling must comply with EU MDR Annex I (Chapter III, Section 23) requirements. Additionally, Croatia mandates that all labeling and Instructions for Use (IFU) intended for patients and laypersons be in **Croatian language**.

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HALMED — Agencija za lijekove i medicinske proizvode

Website: www.halmed.hr | Contact: medpro@halmed.hr | Address: Ksaverska cesta 4, HR-10000 Zagreb, Croatia
Responsible for device registration, market surveillance, and national notifications in Croatia.

LABELING REQUIREMENTS SUMMARY

REQUIREMENT AREA	STATUS	DETAILS & SPECIFICATIONS
UDI (Unique Device Identification)	MANDATORY	Required per EU MDR 2017/745. The UDI consists of a UDI-DI (device identifier, unique to manufacturer + device model) and UDI-PI (production identifier: lot/serial number, expiry date). The UDI carrier (barcode/AIDC) must be placed on the device and/or packaging and be both human-readable (HRI) and machine-readable. Registration in EUDAMED required. Issuing entities: GS1, HIBCC, ICCBBA, IFA. Class III implantables must carry UDI on the device itself.
Electrical Safety Symbol (IEC 60417)	AS APPLICABLE	Required where applicable per EU MDR Annex I and EN ISO 15223-1:2021. Standard IEC 60417 symbols must be used for electrical warnings (double insulation, protective earth, etc.). Symbols must conform to IEC 60601-1 for electromedical devices.
Radio / RF Symbol	AS APPLICABLE	Devices with radio/wireless capabilities must comply with EU Radio Equipment Directive (RED) 2014/53/EU and display applicable RF symbols. CE marking under RED required alongside MDR CE marking when applicable.
Environmental Symbol (WEEE)	REQUIRED	The WEEE crossed-out wheeled bin symbol (ISO 7000-1135) is mandatory for electrical/electronic medical devices per EU Directive 2012/19/EU (WEEE Directive), transposed in Croatia. Croatia implements separate collection and recycling obligations. Symbol placement: outer packaging and, where practical, the device itself.
Authorized Representative / Licence Holder Name	MANDATORY	Non-EU manufacturers must designate an EU Authorized Representative (AR) with a registered place of business in an EU member state. The AR name and address must appear on the label per EU MDR Article 11 and Annex I. The AR must register in the Croatian register of medical device manufacturers (HALMED) as representative. AR must notify HALMED of devices placed on Croatian market within 15 days (prior to full EUDAMED operation).
Country of Origin	AS REQUIRED	EU MDR does not explicitly mandate country of origin on the device label. However, Croatian customs regulations and consumer protection laws may require country of origin on product packaging for non-food products. Best practice: include country of manufacture on outer packaging. Confirm with HALMED for specific device categories.
Language Requirements	CROATIAN REQUIRED	All labeling, IFU, and patient-facing documentation intended for patients and laypersons MUST be in Croatian (Hrvatski). For devices intended exclusively for healthcare professionals, information may be in another EU language provided a professional declaration is available. Technical documentation submitted to HALMED may be accepted in English — confirm with HALMED. IFU must be in Croatian per EU MDR Article 10(11) and Croatian language law requirements.

ADDITIONAL REQUIREMENTS & SUMMARY TABLE

REQUIREMENT AREA	STATUS	DETAILS & SPECIFICATIONS
Size / Location of Labeling Elements	AS PER EU MDR	Per EU MDR Annex I, Chapter III: information must be legible, indelible, easily understood by the intended user, and in a clear, easily understandable format. No specific minimum font size mandated but must be clearly readable. UDI carrier must be placed on the label and outer packaging; Class III implantables require UDI on the device itself. CE mark must appear in a visible, legible, and indelible manner on the device or its packaging.
On Device / Direct Packaging	BOTH	Labeling requirements apply to both the device label (if space permits) and the outer/sterile packaging. For small devices, abbreviated labeling is permitted on the device label if the full information is provided on the outer packaging or IFU. Sterile packaging must include sterility indicator and relevant use-by date.
CE Marking	MANDATORY	CE mark is mandatory for market access in Croatia (EU MDR). For Class IIa, IIb, III devices, the Notified Body (NB) identification number must immediately follow the CE mark. The CE mark must appear on the device or its sterile packaging and outer packaging.
Implant Card	CLASS III IMPLANTABLES	Per EU MDR Article 18: manufacturers of implantable devices must provide implant cards to patients. The implant card must include device identification details (name, model, serial number, UDI) and manufacturer/AR information. Must be provided in Croatian (and other EU official languages as applicable).
Other Unique Croatia-Specific Requirements	CROATIA-SPECIFIC	1) HALMED Notification: Class IIa/IIb/III devices and IVDs must be notified to HALMED within 15 days of Croatian market placement (waived if EUDAMED-registered with Croatia listed). 2) Croatian language law: reinforces Croatian language requirement for all consumer-facing labeling. 3) Local distributor: notification can be submitted through a local distributor. 4) Contact: medpro@halmed.hr. 5) Medical Devices Act (OG 76/13) and Ordinance (OG 84/13) still apply for national procedures.

QUICK REFERENCE SUMMARY

COUNTRY	UDI	ELECTRICAL SAFETY SYMBOL	RADIO SYMBOL	ENVIRONMENTAL SYMBOL	AUTH. REPRESENTATIVE	COUNTRY OF ORIGIN	LANGUAGE	SIZE
Croatia	YES	As applicable (IEC 60417 / IEC 60601-1)	As applicable (RED 2014/53/EU)	YES (WEEE Directive)	YES — EU AR required for non-EU manufacturers; registered with HALMED	Not explicitly mandated by MDR; recommended on outer packaging	Croatian mandatory (patients/laypersons); other EU language acceptable for HCPs with declaration	Legible, indelible, easily understood by the intended user, and in a clear, easily understandable format. No specific minimum font size mandated but must be clearly readable. UDI carrier must be placed on the label and outer packaging; Class III implantables require UDI on the device itself. CE mark must appear in a visible, legible, and indelible manner on the device or its packaging.

CONCLUSIONS

Croatia follows EU MDR 2017/745 directly as an EU Member State, meaning the full EU MDR labeling framework applies without adaptation.