

REGULATORY & LABELLING REQUIREMENTS IN THE EUROPEAN UNION ACCESSION COUNTRIES

Country	Labeling Language (Prof Use)	Notified Body Designated	Vigilance / Market Surveillance (MS)	Registration Requirements	Notification for Clinical Investigation
Cyprus	Greek <i>English accepted for MD for professional use</i>	None	Vigilance and MS performed by Competent Authority	Manufacturers / Authorized representatives must register	Within 60 Days
Czech Republic	Czech	2 – AIMD 1 – IVD 6 – MDD	<ul style="list-style-type: none"> Vigilance performed by State Institute for Drugs Control MS performed by State Inspectorate 	<ul style="list-style-type: none"> Manufacturers / Authorized representatives All MD manufactured by Czech manufacturers 	Within 60 Days
Estonia	Estonian	None	MS by MD Inspectorate within the Competent Authority	<ul style="list-style-type: none"> Manufacturers / Authorized representatives Notification of class IIb and III MD required 	Within 60 Days
Hungary	Hungarian	2 – IVD 2 – MDD 2 – AIMD	Vigilance and MS performed by Competent Authority	<ul style="list-style-type: none"> Manufacturers / Authorized representatives Notification of class IIb and III MD required All MD manufactured by Hungarian manufacturers 	Approval Issued by the CA
Latvia	Latvian <i>English & German accepted</i>	None	<ul style="list-style-type: none"> Vigilance guidelines based on MEDDEV 2.12-1 rev 4 MS by MD Inspectorate within the Market Surveillance Bureau <ul style="list-style-type: none"> State Pharmacy Inspection MD State Technical Supervisor Bureau 	<ul style="list-style-type: none"> Manufacturers / Authorized representatives Registry of supplier / distributor kept Notification of class IIb and III MD required 	Within 60 Days
Lithuania	Lithuanian	Yes	<ul style="list-style-type: none"> Vigilance guidelines based on MEDDEV 2.12-1 rev 4 MS by MD Inspectorate within the Competent Authority 	<ul style="list-style-type: none"> Manufacturers / Authorized representatives Notification of class IIb and III MD required 	Within 60 Days
Malta	English	None	<ul style="list-style-type: none"> Vigilance: User reporting is not mandatory but encouraged; Reporting of certain types of incidents mandatory for Manufacturers MS: Divided among CA: Market Surveillance directorate and Ministry for competitiveness and communications 	<ul style="list-style-type: none"> Manufacturers / Authorized representatives Notification of class IIb and III MD required 	Within 60 Days
Poland	Polish	1 – AIMD 3 – IVD 3 – MDD	Vigilance and MS performed by the Competent Authority	<ul style="list-style-type: none"> Manufacturers / Authorized representatives Notification of Class IIb and III MD required IVDs – list A, list B, self-testing All MD manufactured by Polish manufacturers 	Within 60 Days
Slovak Republic	Slovakian	1 – IVD 1 – MDD 4 – AIMD	<ul style="list-style-type: none"> Vigilance requirements by Governmental Decrees MS within the Competent Authority 	<ul style="list-style-type: none"> Manufacturers / Authorized representatives Registry of supplier / distributor kept Notification of class IIb and III MD required 	Within 60 Days
Slovenia	Slovenian <i>English accepted for devices to be used exclusively by professional medical staff</i>	1 – MDD	<ul style="list-style-type: none"> Vigilance divided between Competent Authority and Center for Poisoning MS performed by Competent Authority 	<ul style="list-style-type: none"> Manufacturers / Authorized representatives Suppliers / Distributors of MD with HQ in Slovenia Slovenian manufacturers of MD – Class I 	Approval Issued by the CA

PLEASE NOTE: *Although this information has been compiled from regulatory sources, it is not intended to be exhaustive. For detailed and definitive information about a country's laws and policies, the government of the country should be consulted. Competent Authority contact information can be found at www.medical.crimsonlanguage.com*

Directives Transposed	CY	CZ	EE	HU	LT	LV	MT	PL	SK	SI
MDD - 93/42/EEC	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ
AIMDD - 90/385/EEC	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ
IVDD - 98/79/EEC	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ
92/59/EEC: Directive on General Product Safety	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ		Δ
93/68/EEC: Council Amendment to many directives including 90/385	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ		Δ
2000/70/EC: Amendment to Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ		Δ
2001/104EC: Amendment to Council Directive as regards to human blood	Δ	Δ	Δ	Δ	Δ	Δ	Δ	Δ		Δ
2003/12/EC: Reclassification of Breast Implants	Δ	Δ	Δ	Δ	Δ	Δ	Δ			Δ
2003/32/EC: MD manufactured utilizing tissues of animal origin		Δ	Δ	Δ	Δ	Δ				Δ

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