

EU LABELING LANGUAGE REQUIREMENTS & COMPETENT AUTHORITIES

Country	Labeling Language Requirement	Competent Authority (by Category)	
Austria	German	AIMD	Federal Ministry of Health and Women Medical Device Dept. Radetzkystrasse 2; A-1030 Vienna, Austria Phone: +43 1 711 00-0 Web: www.bmgf.gv.at (<i>German only</i>)
		MD	
		IVD	
Belgium	Dutch French German	AIMD	Service Public Fédéral Santé Publique (Ministry of Public Health) Directorate General Medicinal Products Amazone Building, Second floor Avenue Bischoffsheim, 33 B-1000 Brussels, Belgium Phone: +32 2 227 55 00 Web: www.afigp.fgov.be
		MD	
		IVD	
Cyprus	Greek <i>English accepted for Professional use devices</i>	AIMD	Cyprus Medical Devices Competent Authority John Kennedy 18 JUKI Building 1446 Pallouriotissa - Nicosia, Cyprus Phone: +357 22 468427
		MD	
		IVD	
Czech Republic	Czech	AIMD	Ministry of Health Palackeho namesti 4, 128 01 Prague 2 Czech Republic Phone: +420 224 971 111 Web: www.mzcr.cz (<i>Czech only</i>)
		MD	
		IVD	
Denmark	Danish	AIMD	Danish Medicines Agency Axel Heides Gade 1 DK-2300 København S, Denmark Phone: +45 44 88 95 95 Web: www.medicaldevices.dk
		MD	
		IVD	
Estonia	Estonian	AIMD	State Agency of Medicines 19 Ravila St., 50411 Tartu Estonia Phone: +372 7 37 4140 Web: www.sam.ee
		MD	
		IVD	
Finland	Finnish Swedish	AIMD	National Agency for Medicines, Medical Devices Mannerheimintie 166 P.O. Box 55, FIN-00301 Helsinki, Finland Phone: +358 9 47 3341 Web: www.nam.fi/english/
		MD	
		IVD	
France	French	AIMD	Agence française de sécurité sanitaire des produits de santé (AFSSAPS) French Health Products Safety Agency 143-147 boulevard Anatole France 93285 Saint Denis Cedex, France Phone: +33 1 55 87 30 00 Web: http://afssaps.sante.fr/ang/indang.htm
		MD	
		IVD	
Germany	German	AIMD	Federal Institute for Drugs and Medical Devices Kurt Georg Kiesinger Allee 3 D53175 Bonn, Germany Phone: +49 228 207 5384 (30) Web: www.bfarm.de/en/index.php
		MD	
		IVD	
Greece	Greek	AIMD	National Organization for Medicines 284 Mesogion Ave 155 62 Athens, Greece Phone: +30 21 65 07 200 Web: www.eof.gr/eof_en/enhome.html
		MD	
		IVD	
Hungary	Hungarian	AIMD	Authority for Medical Devices Budapest, Pf. 987. H-1245, Hungary Phone: +36 1 302 5060 Web: http://amd.eszcsm.hu/index_eng.html
		MD	
		IVD	
Ireland	English	AIMD	Irish Medicines Board, Medical Devices Department Earlsfort Centre, Earlsfort Terrace Dublin 2, Ireland Phone: +353 1 676 4971 Web: www.medicaldevices.ie
		MD	
		IVD	

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Italy	Italian	AIMD	Ministry of Health Dipartimento dell'innovazione Direzione Generale dei Farmaci e Dispositivi Medici Piazzale dell'Industria 20 0144 Roma, Italy Phone: +39 06 5994 3809 Web: www.sanita.it (<i>Italian Only</i>)
		MD	
		IVD	
Latvia	Latvian <i>English or German accepted for Professional use devices</i>	AIMD	Health Ministry of Latvia Health Statistics & Medical Technologies Agency (CA) 12/22 Dantes Street, Riga, -LV-1005, Latvia Phone: +271 750 1590 Web: www.vsmta.lv (<i>Latvian Only</i>)
		MD	
		IVD	
Lithuania	Lithuanian	AIMD	State Health Care Accreditation Service Ministry of Health of the Republic of Lithuania Service Z. Liauksmino str. 5 LT- 2600 Vilnius, Lithuania Phone: +370 52 61 51 77 Web: www.sam.lt/vaspvt (<i>Lithuanian Only</i>)
		MD	
		IVD	
Luxembourg	French German Liezeburgish	AIMD	Ministère de la Santé Allée Marconi / Villa Louvigny L-2120 Luxembourg Phone: +352 478 56 34 Web: www.ms.etat.lu (<i>French Only</i>)
		MD	
		IVD	
Malta	Maltese or English	AIMD	Malta Standards Authority Second Floor, Evans Building Merchants Street, Valletta VLT 03, Malta Phone: +356 2124 2420 Web: www.msa.org.mt
		MD	
		IVD	
Netherlands	Dutch	AIMD	Healthcare Inspectorate Parnassusplein 5 2511 VX The Hague, The Netherlands Phone: +38 467 1820 Web: www.igz.nl/indexie.html
		MD	
		IVD	
Poland	Polish	No Competent Authority as of December, 2004	
Portugal	Portuguese	AIMD	Instituto Nacional de Saude Av. Padre Cruz 1649-016 Lisbon, Portugal Phone: +351 21 751 9200 Web: www.insarj.pt (<i>Portuguese Only</i>)
		MD	
		IVD	
Slovakia	Slovak	No Competent Authority as of December, 2004	
Slovenia	Slovenian <i>English accepted with IFUs for devices used exclusively by professional medical staff</i>	AIMD	Agency for Medicinal Products and Medicinal Devices of the Republic of Slovenia Mali trg 6, 1000 Ljubljana Slovenia Phone: +386 1 478 6240 Web: www2.gov.si/mz/mz-splet.nsf (<i>Slovenian Only</i>)
		MD	
		IVD	
Spain	Spanish	AIMD	Ministerio Sanidad y Consumo Agencia Española de Medicamentos y Productos Sanitarios Calle Alcalá, 56 28071 Madrid, Spain Phone: +34 91 822 5018 Web: www.agemed.es (<i>Spanish Only</i>)
		MD	
		IVD	
Sweden	Swedish	AIMD	Medical Products Agency Medical Devices P.O. Box 26 SE-751 03 Uppsala, Sweden Phone: +46 18 174 600 Web: www.mpa.se/eng/index.shtml
		MD	
		IVD	
United Kingdom	English	AIMD	Medicines and Healthcare Products Regulatory Agency (MHRA) Hannibal House, Elephant and Castle London SE1 6TQ, United Kingdom Phone: +44 20 7084 2000 Web: www.mhra.gov.uk
		MD	
		IVD	

Information subject to change
For updates: www.medical.crimsonlanguage.com



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