

# IVDD Product Registration in Europe

July 2019

		Who shall register?	Risk Classes	Comments	Costs involved
Austria	AT	MedNet into DIMDI	all classes	German registration valid	n.a.
<b>Belgium</b>	BE	<b>MedNet to notify separately</b>	<b>all classes</b>		<b>€ 120 per product group</b>
<b>Bulgaria</b>	BG	<b>Voluntary notification (or on demand by local authority) by Bulgarian distributor</b>	<b>all classes</b>	<b>Sales only via registered wholesaler</b>	n.a.
<b>Croatia</b>	HR	<b>MedNet to notify separately</b>	<b>all classes</b>		<b>€ 120 per product group</b>
Cyprus	CY	MedNet into DIMDI	all classes	German registration valid	n.a.
Czech Republic	CZ	MedNet into DIMDI	all classes	German registration valid	n.a.
Denmark	DK	MedNet into DIMDI	all classes	German registration valid	n.a.
Estonia	EE	MedNet into DIMDI	all classes	optional notification to Estonia	n.a.
<b>Finland</b>	FI	<b>MedNet to notify separately</b>	<b>self testing</b>		<b>€ 120 per product group</b>
France	FR	MedNet into DIMDI	all classes	German registration valid	n.a.
Germany	DE	MedNet into DIMDI	all classes	German registration valid	n.a.
<b>Greece</b>	GR	<b>MedNet to notify separately</b>	<b>all classes</b>		<b>€ 120 per product group</b>
Hungary	HU	MedNet into DIMDI	all classes	German registration valid	n.a.
Ireland	IE	MedNet into DIMDI	all classes	German registration valid	n.a.
<b>Italy</b>	IT	<b>MedNet to notify separately</b>	<b>Annex II + self testing</b>		<b>€ 120 per product group</b>
<b>Latvia</b>	LV	<b>MedNet to notify separately</b>	<b>Annex II + self testing</b>		<b>€ 120 per product group</b>
Lithuania	LT	MedNet into DIMDI	all classes	German registration valid	n.a.
Luxembourg	LU	MedNet into DIMDI	all classes	German registration valid	
Malta	MT	MedNet into DIMDI	all classes	German registration valid	n.a.
Netherlands	NL	MedNet into DIMDI	all classes	German registration valid	n.a.
Poland	PL	MedNet into DIMDI	all classes	German registration valid	n.a.
<b>Portugal</b>	PT	<b>MedNet to register into local database/ wholesaler/distributor also required to register</b>	<b>Annex II + self testing</b>		<b>€ 120 per product group</b>
Romania	RO	MedNet into DIMDI	all classes	German registration valid	n.a.
Slovakia	SK	MedNet into DIMDI	all classes	German registration valid	n.a.
Slovenia	SI	MedNet into DIMDI	all classes	German registration valid	n.a.
<b>Spain</b>	ES	<b>Spanish distributor/for direct marketing MedNet or manufacturer to register into local database</b>	<b>Annex II + self testing</b>		<b>€ 475 per product group</b>
Sweden	SE	MedNet into DIMDI	all classes	German registration valid	n.a.
United Kingdom	UK	MedNet into DIMDI	all classes	German registration valid	n.a.
<b>EFTA countries</b>					
Iceland	IS	MedNet into DIMDI	all classes	German registration valid	n.a.
Liechtenstein	LI	<b>MedNet to notify separately</b>	<b>all classes</b>		<b>€ 120 per product group</b>
Norway	NO	MedNet into DIMDI	all classes	German registration valid	n.a.
Switzerland	CH	MedNet into DIMDI	all classes	German registration valid	n.a.