Actor information notification form for distributors of medical devices

This operator information notification form for distributors of medical devices shall be duly completed and sent to Fimea's service mailbox at laiterekisteri@fimea.fi. Fimea will send the Fimea operator reference number to the submitter by e-mail.

A. Basic information	Legislation ☐ MDR ☐ IVDR ☐ IVDD ☐ National regulation
	Type of notification [2*] ☐ New Actor ☐ Change in operator information
	The date of your latest confirmation of data

[1] Indicate the legislation applicable to the operator, MDR = Regulation (EU) 2017/745, IVDR = Regulation (EU)2017/746, IVD = Directive 98/79/EC, National = Medical Devices Act 719/2021. You can select more than one applicable legal provision.
[2] Indicate whether this notification pertains to a new operator or a change to operator information. A change notification must be submitted for any changes to the notified information.

B. Operator information	The submitter's role is [3*] ☐ Distributor[4] ☐ Importer to Finland (e.g. sel-test) [5]	
	Operator's name*	
	Fimea's actor reference number [6]	
	Operator's abbreviation	
	EORI number [7]	VAT number
	Street name and number*	
	Postal code*	City*
	PO Box	Country*
	E-mail address*	Public telephone number
	Public e-mail address	Operator's public Web address
	Further information	

[3] The liability to file a notification pertains to all distributors liable to file a notification, not only those who are based in Finland.
[4] Indicate the distributor who distributes medical devices to retailers, healthcare and social welfare operators and other professional users.
[5] Indicate the distributor who imports to the market a device intended for self-testing or a device containing substances of human origin.
[6] Fimea's reference numbers will be notified to the operator when the notification has been processed. Fimea' operator reference number must be given if you are submitting an operator's change notification.
[7] EORI number: All companies and persons involved in trade on the EU market must have an EORI number that can be found from the EORI database (https://ec.europa.eu/taxation_customs/dds2/eos/eori_home.jsp?Lang=fi). If you or your company do not have an EORI number, contact the customs authorities of your home country (https://ec.europa.eu/taxation_customs/customs-4/union-customs-code/national-customs-administrations_en).

C. Operator's contact person information	First name*	Last name*
	Telephone number*	E-mail address*

E. Invoicing information [9]	Invoicing organisation	
	Street name and number	
	Postal code	City
	VAT number	Country
	Invoicing language	
	Telephone number	E-mail address
	e-Invoicing address	Operator ID

[9] Indicate the invoicing details if different from those in section "B Operator information".

F. Submitter information [10]	Submitter's organisation	
	First name	Last name
	Telephone number	E-mail address

[10] Indicate the submitter information if you are filing the notification on behalf of the operator

As the submitter, I hereby declare that I am authorised to give this information on behalf of the actor*		

Date of the notification:

The Finnish Medicines Agency will not separately acknowledge the receipt of the notification.