## MDCG 2024 - 16

## **Manufacturer Information Form**

on Interruption or Discontinuation of Supply of certain medical devices and certain *in vitro* diagnostic medical devices

(as per Article 10a of Regulation (EU) 2024/1860 amending Regulation (EU) 2017/745 and Regulation (EU) 2017/746)

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission. The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Note: this form should be completed where reporting on individual or several devices of the same manufacturer. For reporting on several devices, only one form should be completed and see section 6 for further instruction. See also Q.11 and Q.12 of 'Q&A' Obligation to inform in case of interruption or discontinuation of supply'. For the purposes of this form, no personal data should be submitted or collected, including contact details.

1 Administrative information	
Name of National Competent Authority (NCA) to which this repo	t is sent
Type of information	
O Initial information	
Additional information (voluntary)*	
Follow-up information (voluntary)*	
*Please specify modified sections of the form	
(if additional or follow-up information):	
Date of information	
Reference number assigned by the manufacturer (if any)	
Reference number assigned by NCA (as applicable)	
2 Information on submitter of the report	
Status of submitter	
Manufacturer	
<ul> <li>Authorised Representative (if mandated to act on behalf</li> </ul>	of the manufacturer)
<ul> <li>Other entity (if acting on behalf of the manufacturer)</li> </ul>	
3 Manufacturer Information	
Manufacturer Information  Manufacturer organisation name	
Single registration number (if filled here and already EUDAMED)	registered inlease leave following fields in this section 3 onen)
Single registration number (if filed field and already EODAWED)	egistered, predictioned following fields in this section is open,
Address	
Postcode	City
Phone	Fax
E-mail	Country

4 Authorized Representative Inform	ation (if applicable)
Authorised representative organisation name (if m	nandated to make this report on behalf of the manufacturer)
Single registration number (if filled here and alread	ly EUDAMED registered, please leave following fields in this section 4 open)
Address	
Postcode	City
Phone	Fax
E-mail	Country
5 Other entity (if applicable)	
Organisation (if completing this report on behalf or	f the manufacturer)
Address	
Postcode	City
Phone	Fax
E-mail	Country

## 6 Medical device information Risk class of device MDD/AIMDD IVDD AIMD Active implant MDD Class III IVD Annex II List A MDD Class IIb IVD Annex II List B MDD Class IIa IVD for self-testing MDD Class I sterile MDD Class I sterile MDD Class I measuring function

MDR

Class III

Class D

Class C

Class IIa

Class B

Class I

Class I

Class I

Class I sterile

Class I measuring function

Class I reusable surgical instruments

Device Identification	
Please fill this section when reporting on an individual device.	
Where reporting on several devices, complete the 'MDCG 2024-1	6 Annex - Device Identification Table'.
Reports on several devices should be for the same manufacturer,	the same interruption or discontinuation and same
associated reason (See 'reasons' in section 7).	
Unique Device Identification (UDI-DI)/EUDAMED ID (if applicable	e)
Basic UDI-DI/Eudamed-DI (if applicable)	
If the above UDI section is completed and the device is already r	egistered in EUDAMED, please leave the following fields blank
and go to 'Intended use' field.	
If filling out the following fields for devices without UDI-DI/ EUD.	AMED DI, please complete all mandatory fields.
Model	Catalogue/reference number
Nomenclature system (e.g. EMDN)	Nomenclature code
Nomenclature text	
Commercial name/ brand name / proprietary or common name	
Intended use according to the IFU or add IFU in attachment (vol	untary)

7 Description of the Interruption or discontinuation of supply (information requested as per Art 10a)
Specify if the report concerns an interruption or discontinuation
o Interruption
o Discontinuation
Reason for the Interruption or Discontinuation of Supply
please select:
Regulatory issue
Supply chain issue
Manufacturing issue
Other
Specify other:
Additional information on reason for the interruption or discontinuation of supply (voluntary)
realistic mornialist on reason to the interruption of absorbing to supply (voluntary)
Information on the assessment of the situation (If available)
Device used in a serious, acute or chronic pathology, life- sustaining or life-saving device or accessory
Intended for a specific population (e.g., vulnerable populations such as paediatric or geriatric patients)
Disruption or interruption limiting / preventing the patients from accessing treatment
Device without or with limited available alternatives, or consumable device not replaceable by any other type/brand
Major market share in one or several members states
Other
Additional information on the assessment of the situation (if available)
Additional information on the assessment of the steation (if available)
Duration
When is the interruption/discontinuation of supply estimated to start?
When is the interruption estimated to end (if available)?
Note: Where the estimated start date differs in case of reporting on several devices, please complete the dedicated field in the
'MDCG 2024-16 Annex - Device Identification Table'. The same applies for interruptions where end date is provided.
Additional information about the estimated duration, if the start date and the duration is disclosed (voluntary):
Estimated point in time for resumption of supply of the devices (where known and appropriate)

The medical	l device	is usually	/ market	ed and su	ipplied to	o the folio	owing cou	iiiliies. (vo	Jiuiitaiyj			
All E	EA, Turk	ey and N	lorthern l	Ireland								
AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR
HU	E IE	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT
RO	SE	SI	SK	TR	XI							
Others:							The	e code XI is	used for	Northern I	reland	
The countri	es that	are impa	cted by t	he interru	uption/dis	continuat	ion:					
All EE	A, Turke	y and No	orthern Ir	eland								
AT [	■ BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR
■HU	IE IE	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT
RO [	SE	SI	SK	TR	XI							
Others:							The	code XI is i	used for N	lorthern Ire	eland	
Information	Notifica	ition(s) re	garding t	he interri	uption or	discontin	uation of	supply ha	ive been	sent:		
Notification	. to 111/11	CDC		]vaa	DNA F		واطوونا	Da	to Cont /	DD /B4B4 /\	ΛΛ	
Notification Notification	•	ICPS		Yes Yes	No No	Not App				DD/MM/\ DD/MM/\		
Notification Notification	_	orters		Yes	No	Not App	licable	Da	te Sent (	DD/MM/Y	(Y)	
Notification to distributors Yes No Not Applicable Date Sent (DD/MM/YY)  Attached files (Voluntary)												
				-	= =	= -						
Attached fil	es (Volu	ntary)	ion on	Yes	No [	Not App	olicable	Da	te Sent (I	DD/MM/\	(Y)	
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