

## 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.*

<b>1 Administrative information</b>	
<b>Name of National Competent Authority (NCA) to which this report is sent</b>	
<b>Type of information</b>	
<input type="radio"/> Initial information <input type="radio"/> Additional information (voluntary)* <input type="radio"/> Follow-up information (voluntary)*	
*Please specify modified sections of the form (if additional or follow-up information):	
<b>Date of information</b>	
<b>Reference number assigned by the manufacturer (if any)</b>	
<b>Reference number assigned by NCA (as applicable)</b>	

<b>2 Information on submitter of the report</b>	
<b>Status of submitter</b>	
<input type="radio"/> Manufacturer <input type="radio"/> Authorised Representative (if mandated to act on behalf of the manufacturer) <input type="radio"/> Other entity (if acting on behalf of the manufacturer)	

<b>3 Manufacturer Information</b>	
<b>Manufacturer organisation name</b>	
<b>Single registration number (if filled here and already EUDAMED registered, please leave following fields in this section 3 open)</b>	
<b>Address</b>	
<b>Postcode</b>	<b>City</b>
<b>Phone</b>	<b>Fax</b>
<b>E-mail</b>	<b>Country</b>

<b>4 Authorized Representative Information (if applicable)</b>	
<b>Authorised representative organisation name</b> (if mandated to make this report on behalf of the manufacturer)	
<b>Single registration number</b> (if filled here and already EUDAMED registered, please leave following fields in this section 4 open)	
<b>Address</b>	
<b>Postcode</b>	<b>City</b>
<b>Phone</b>	<b>Fax</b>
<b>E-mail</b>	<b>Country</b>

<b>5 Other entity (if applicable)</b>	
<b>Organisation</b> (if completing this report on behalf of the manufacturer)	
<b>Address</b>	
<b>Postcode</b>	<b>City</b>
<b>Phone</b>	<b>Fax</b>
<b>E-mail</b>	<b>Country</b>

**6 Medical device information**

**Risk class of device**

<p><b><u>MDD/AIMDD</u></b></p> <p><input type="radio"/> AIMD Active implant</p> <p><input type="radio"/> MDD Class III</p> <p><input type="radio"/> MDD Class IIb</p> <p><input type="radio"/> MDD Class IIa</p> <p><input type="radio"/> MDD Class I</p> <p><input type="radio"/> MDD Class I sterile</p> <p><input type="radio"/> MDD Class I measuring function</p>	<p><b><u>IVDD</u></b></p> <p><input type="radio"/> IVD Annex II List A</p> <p><input type="radio"/> IVD Annex II List B</p> <p><input type="radio"/> IVD for self-testing</p> <p><input type="radio"/> IVD general</p>
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<p><b><u>MDR</u></b></p> <p><input type="radio"/> Class III</p> <p><input type="radio"/> Class IIb</p> <p><input type="radio"/> Class IIa</p> <p><input type="radio"/> Class I</p> <p><input type="radio"/> Class I sterile</p> <p><input type="radio"/> Class I measuring function</p> <p><input type="radio"/> Class I reusable surgical instruments</p>	<p><b><u>IVDR</u></b></p> <p><input type="radio"/> Class D</p> <p><input type="radio"/> Class C</p> <p><input type="radio"/> Class B</p> <p><input type="radio"/> Class A</p> <p><input type="radio"/> Class A sterile</p>
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**Device Identification**

Please fill this section when reporting on an individual device.  
 Where reporting on several devices, complete the 'MDCG 2024-16 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).

<b>Unique Device Identification (UDI-DI)/EUDAMED ID (if applicable)</b>	
<b>Basic UDI-DI/Eudamed-DI (if applicable)</b>	

If the above UDI section is completed and the device is already registered 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/ EUDAMED DI, please complete all mandatory fields.

<b>Model</b>	<b>Catalogue/reference number</b>
<b>Nomenclature system (e.g. EMDN)</b>	<b>Nomenclature code</b>

**Nomenclature text**

**Commercial name/ brand name / proprietary or common name**

**Intended use according to the IFU or add IFU in attachment (voluntary)**

<p><b>7 Description of the Interruption or discontinuation of supply (information requested as per Art 10a)</b></p> <p><i>Specify if the report concerns an interruption or discontinuation</i></p> <ul style="list-style-type: none"> <li><input type="radio"/> Interruption</li> <li><input type="radio"/> Discontinuation</li> </ul>
<p><b>Reason for the Interruption or Discontinuation of Supply</b></p> <p>please select:</p> <ul style="list-style-type: none"> <li><input type="radio"/> Regulatory issue</li> <li><input type="radio"/> Supply chain issue</li> <li><input type="radio"/> Manufacturing issue</li> <li><input type="radio"/> Other</li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p><b>Specify other:</b></p> </div>
<p><b>Additional information on reason for the interruption or discontinuation of supply (voluntary)</b></p>
<p><b>Information on the assessment of the situation (If available)</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> Device used in a serious, acute or chronic pathology, life- sustaining or life-saving device or accessory</li> <li><input type="radio"/> Intended for a specific population (e.g., vulnerable populations such as paediatric or geriatric patients)</li> <li><input type="radio"/> Disruption or interruption limiting / preventing the patients from accessing treatment</li> <li><input type="radio"/> Device without or with limited available alternatives, or consumable device not replaceable by any other type/brand</li> <li><input type="radio"/> Major market share in one or several members states</li> <li><input type="radio"/> Other</li> </ul>
<p><b>Additional information on the assessment of the situation (if available)</b></p>
<p><b>Duration</b></p> <p><b>When is the interruption/discontinuation of supply estimated to start?</b></p> <p><b>When is the interruption estimated to end (if available)?</b></p> <p><i>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.</i></p>
<p><b>Additional information about the estimated duration, if the start date and the duration is disclosed (voluntary):</b></p> <p><b>Estimated point in time for resumption of supply of the devices (where known and appropriate)</b></p>

**The medical device is usually marketed and supplied to the following countries: (voluntary)**

All EEA, Turkey and Northern Ireland

AT  BE  BG  CY  CZ  DE  DK  EE  ES  FI  FR  GR  HR

HU  IE  IS  IT  LI  LT  LU  LV  MT  NL  NO  PL  PT

RO  SE  SI  SK  TR  XI

Others:  The code XI is used for Northern Ireland

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**The countries that are impacted by the interruption/discontinuation:**

All EEA, Turkey and Northern Ireland

AT  BE  BG  CY  CZ  DE  DK  EE  ES  FI  FR  GR  HR

HU  IE  IS  IT  LI  LT  LU  LV  MT  NL  NO  PL  PT

RO  SE  SI  SK  TR  XI

Others:  The code XI is used for Northern Ireland

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**Information Notification(s) regarding the interruption or discontinuation of supply have been sent:**

Notification to HI/HCPS	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable	Date Sent (DD/MM/YY)
Notification to AR	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable	Date Sent (DD/MM/YY)
Notification to importers	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable	Date Sent (DD/MM/YY)
Notification to distributors	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable	Date Sent (DD/MM/YY)

Attached files (Voluntary)

**8 Additional information on Interruption or Discontinuation of Supply (voluntary)**

**This section allows manufacturer, on voluntary basis or on the request of a competent authority, to share additional information**

Possible mitigations measures: *to reduce the impact of the interruption or discontinuation of supply.*

Is the redistribution of EU or Global stocks an option?  Yes  No

Do you manufacture a similar alternative product with a similar intended purpose?  Yes  No

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**Details of the remaining inventory / existing stock level at EU level**

If applicable, please provide information in attached file

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**Progress update on the interruption or discontinuation of supply**