

Distribution of Coloplast Medical Devices in the EEA

Best Practice Guide for Distributors

Purpose

This Guide outlines the Coloplast (Manufacturer) requirements for Distributors making Coloplast's medical devices (Devices) available within the European Economic Area (EEA). Its purpose is to support compliance with the Medical Device Regulation (EU) 2017/745 (MDR), while ensuring safe, compliant, and efficient distribution activities. This Guide is intended to be used alongside all existing legal and regulatory requirements and obligations, as well as applicable commercial agreements and/or terms and conditions.

1. Definitions

1.1 Capitalised terms follow the definitions in MDR Article 2 or elsewhere in the MDR and relevant guidance documents.

2. Compliance and Due Care

2.1 The Distributor shall act with due care, considering MDR requirements, patient and user safety, and the interests of the Manufacturer and all parties in the supply chain.

2.2 The Distributor acknowledges that its actions can affect the regulatory compliance of the Devices. The Manufacturer and the Distributor commit to timely communication and collaboration to ensure compliance and address non-conformities.

3. Verification of Compliance

3.1 Before making a Device available on the market and upon receipt, the Distributor shall verify that:

- Devices are CE marked.
- Devices are accompanied by valid labelling and Instructions for Use (IFU) that meet language requirements, either in printed form and/or made available electronically in accordance with Regulation (EU) 2017/2012, whichever has been deemed applicable by the Manufacturer.
- Devices are covered by a current Declaration of Conformity.
- Importer details are displayed, where applicable.
- UDI carrier is present if required.

3.2 Sampling may be used if representative of the delivery. Sampling methods and rationale must be documented.

3.3 Verification checks must be recorded.

3.4 If the Distributor becomes aware or has reason to believe that any Device is non-conforming, presents a serious risk or may be falsified:

- The Distributor shall immediately quarantine the affected Devices from saleable stock.
- The Distributor shall immediately inform the Manufacturer, Importer, and Authorized Representative (where applicable), and provide relevant details. Where the Distributor is legally required to notify Competent Authorities, it may do so but shall, to the extent permitted by law, coordinate the notification with the Manufacturer.
- The Distributor shall promptly share copies of any communications with Competent Authorities, including any requests, orders, or sample demands, and keep the Manufacturer informed of all follow-up actions.

4. Storage and Transport

4.1 While under the Distributor's responsibility, Devices shall be stored and transported according to the Manufacturer's labelling and IFU requirements.

4.2 If specific storage conditions are required, continuous temperature monitoring should be performed and documented to ensure that appropriate storage conditions are maintained. This applies to all areas where medical devices are stored (e.g. bulk storage, quarantine, return areas, etc.).

4.3 Distributor's storage facilities shall prevent damage, deterioration, contamination, or other adverse effects (e.g., environmental protection, pest control, fire safety).

4.4 Where temperature control is required, monitoring must occur at least daily and records must be retained.

5. Complaint and Incident Handling

5.1 The Distributor must maintain a structured process to collect, record, and handle all complaints about suspected Incidents related to a Device they have made available. This includes all complaints or reports received from healthcare professionals, patients, users, or other stakeholders – whether oral, written, or electronic communications.

5.2 All complaints must be recorded in a register that can be shared upon request. Each entry must include, at minimum:

<i>Date of awareness</i>	Date when the Distributor became aware of the Complaint/Incident.
<i>Device name/item code</i>	Identifier for the device (e.g., product code, catalog number).
<i>Lot/serial numbers</i>	Lot or serial numbers of the affected device(s).
<i>UDI (if applicable)</i>	Unique Device Identifier, if available.
<i>Quantity</i>	Number of devices involved.
<i>Reporter details</i>	Name, contact information
<i>Consignee details</i>	Name and contact information of the recipient of the device.
<i>Description</i>	Description of the Complaint/Incident.

5.3 The Distributor must immediately notify the Manufacturer, Importer, and Authorized Representative (where applicable) of all complaints about suspected Incidents. The Distributor shall not submit Incident Reports to Competent Authorities without the Manufacturer's prior agreement, unless legally required.

5.4 The Distributor must support the Manufacturer in investigating Complaints, Incidents and Serious Incidents, providing all relevant information and documentation.

5.5 The Distributor must collaborate with the Manufacturer to implement Corrective and Preventive Actions (CAPAs) as needed.

6. Traceability, Tracking and Corrective Action

6.1 The Distributor shall cooperate with the Manufacturer and its Authorized Representative (where applicable) to ensure appropriate traceability.

6.2 The Distributor shall establish and maintain a traceability system enabling identification of:

- Upstream suppliers (including importers)
- Downstream economic operators, health institutions, and healthcare professionals;
- Devices supplied (including UDI where applicable).

6.3 The Distributors must keep adequate records, including records of customers and suppliers to and from whom medical devices have been distributed. Such transaction records must include, at minimum:

<i>Device name/item code</i>	Identifier for the device (e.g., product code, catalog number).
<i>Lot/serial numbers</i>	Lot or serial numbers of the devices.
<i>UDI (if applicable)</i>	Unique Device Identifier, if available.
<i>Quantities</i>	Number of devices supplied or received.
<i>Delivery date</i>	Date when the devices were shipped or received.
<i>Customer/supplier details</i>	Name, address, and contact information of the customer or supplier.

6.4 The Distributor must keep a register of Complaints, of Non-Conforming devices and of Recalls and Withdrawals, and keep the Manufacturer, the Authorised Representative and the Importer (where applicable) informed of such monitoring and provide them with any information upon their request.

6.5 The Distributor shall implement Field Safety Corrective Actions (FSCAs), Recalls, or Withdrawals as instructed by the Manufacturer, and in accordance with the defined timeline.

6.6 No unilateral FSCA, Recall, or Withdrawal may be implemented without the Manufacturer's written approval.

6.7 If the Distributor becomes aware of a situation potentially requiring FSCA or Recall, it must promptly notify the Manufacturer and support the assessment.

6.8 The Manufacturer reserves the right to conduct mock recalls as part of the monitoring of its quality management system.

7. Cooperation with Competent Authorities

7.1 Any request for information or cooperation from a Competent Authority shall be immediately forwarded to the Manufacturer.

7.2 If authorities request samples or access to Devices, the Distributor shall notify the Manufacturer and facilitate the Manufacturer's presence.

7.3 Where authorities request evidence of MDR conformity, the Manufacturer may elect to respond directly.

7.4 Distributor shall provide Competent Authorities with access to relevant records upon request (e.g., traceability records).

8. Registrations

8.1 The Distributor shall maintain all national or local registrations required and provide evidence to the Manufacturer upon request, where applicable.

9. Marketing and Promotional Claims

9.1 Communication about the Devices must:

- Reflect only the approved intended purpose, safety, and performance.
- Not be misleading by overstating functions or suggesting unauthorised uses.
- Comply with all applicable national rules and regulations, including those governing advertising of medical devices.

9.2 If the Distributor communicates externally about activities involving the Devices, all content must align with the Manufacturer's approved product information.

10. Relabelling & Repackaging

10.1 Distributors may relabel or repackage a Device only when this is necessary in order to make the Device available on the market in the relevant Member State. When doing so, they must fully comply with the obligations set out in Article 16(2) of MDR, including:

- Ensuring the Device's original condition is not adversely affected by the relabelling or repackaging activity.
- Implementing an appropriate quality management system covering these operations.
- Ensuring that the translated information (if applicable) is accurate, up-to-date, and derived from the original Manufacturer content.
- Notifying both the Manufacturer and the Competent Authority before making the relabelled/repackaged Device available on the relevant Member State market, in line with the timelines and information requirements defined in Article 16(4) of MDR.
- Only the activities strictly required to make the device available on a given Member State market – such as adding language-specific labelling, translating the IFU, or adapting packaging – are permitted.

11. Returned Devices

11.1 The Distributor must establish and maintain a structured process for handling returned Devices.

11.2 Returned Devices shall be quarantined upon receipt and assessed for potential risks (e.g., contamination, damage, or misuse). Returned products may only be reintroduced into stock if:

- They are visibly undamaged and in their original packaging.
- Their shelf life/expiry date has not been compromised.
- They have been stored and transported under appropriate conditions.
- They are accompanied by documentation confirming their history (e.g., reason for return, storage conditions).

11.3 Devices that do not meet these criteria must be disposed of in accordance with local regulations.

11.4 Any Device returned in relation to suspected of non-conformity or Incident shall follow the process and requirements set out in Section 5.

11.5 Records of returned medical devices must be documented, including as a minimum:

<i>Date of return</i>	Date when the product was returned.
<i>Product details</i>	Device name, item code, lot/serial number, UDI (if applicable).
<i>Reason for return</i>	Description of why the product was returned (e.g., defect, excess stock).
<i>Assessment/outcome</i>	Decision on whether the product can be reintroduced or must be disposed of.

12. Records, Retention and Audit

12.1 Distribution, traceability, verification, storage, complaint, incident and serious incident records must be retained for at least 10 years after the last Device has been placed on the market, and of at least 15 years in the case of Implantable Devices. These records may be requested by the Competent Authorities.

12.2 The Manufacturer may audit the Distributor's relevant records and facilities upon reasonable notice. Such audits may be carried out by the Manufacturer, by any of its affiliates, or by independent third parties appointed by the Manufacturer, provided that such third parties are bound by appropriate confidentiality obligations.

12.3 The Distributor shall provide access to knowledgeable personnel and copies of requested documents.

12.4 Traceability and Complaint data are not subject to confidentiality restrictions.

13. Outsourcing and Sub-distribution

13.1 If the Distributor outsources warehousing, logistics, data processing, or other activities relevant to compliance, it must ensure – via contractual controls – that service providers meet the same quality and regulatory requirements.

13.2 If the Distributor supplies other distributors (e.g., wholesalers, retailers), those parties must also meet equivalent

requirements.

13.3 Copies of such contracts must be provided to the Manufacturer upon request (commercial terms may be redacted).

14. Market Access

14.1 Devices placed on the market by the Manufacturer within the EEA are solely intended for sale within the EEA and shall not be sold outside the EEA unless the Manufacturer has authorised such sales, as it may compromise the ability of the Manufacturer to demonstrate continued compliance with local regulatory requirements and potentially affect traceability and patient safety.

15. Product Liability Claims for Defective Devices

15.1 The Distributor shall promptly notify the Manufacturer of any product liability claims received.

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