



July 31st, 2025

Notice of BD[®] Connecta[™] Stopcock product family label updates

Dear Valued Customer,

Our records indicate that you have historically purchased the following BD Connecta[™] Stopcocks and Extension Sets. In our continuing effort to improve our accessories offerings we have implemented some changes to the BD Connecta[™] Stopcock Family due to MDR compliance requirements, manufacturing capacity optimization, and improved product labelling.

What to expect?

MDR Compliant products with the following changes implemented:

- **Legal Manufacturer change:**
 - As of August 2024, the legal manufacturer office changed from Helsingborg, Sweden to Eysins, Switzerland.
 - This change coincides with the transition to MDR CE-marked products.
- **MDR Compliance changes:**
 - Priming volumes and set lengths have been updated and included on the product labels.
 - Material formulations now printed on every BD Connecta[™] Extension Sets label. e.g., Polyvinyl chloride (PVC).
 - Instruction for Use (IFU) label increased in size.
 - Products now specify rotation angles in degrees, such as 360°.
 - Compliant to ISO 80369-7:2021: Small-bore connectors for liquids and gases in healthcare applications. This standard aims to ensure safety by preventing misconnections between different types of connectors used in medical devices.

What this means for you?

- The updated Connecta[™] products are now fully compliant with ISO 80369-7:2021.
- These changes may result in minor differences in the luer connector design, which are intended to enhance compatibility and reduce the risk of misconnections.
- Affected SKUs and their corresponding lot numbers have been documented and are available upon request.
- ISO 80369-7:2021 is backward compatible with ISO 80369-7:2016. This means that devices compliant with the 2021 version are designed to safely connect with those compliant with the 2016 version.

- In cases where non-compliant components are used, there may be an increased risk of leakage, and we advise customers to verify compatibility during product integration.
- The changes have been notified to BSI, our notified body and to country regulatory authorities when needed.

Customer support and resources:

- A revised FAQ document has been prepared to address common questions and support your teams during this transition.
- Our regional marketing and regulatory teams are available to assist with any specific inquiries or documentation needs, including tender submissions and product registrations.

Figure 1: Example of a new label



* * *

We appreciate your continued partnership and are committed to supporting a smooth transition to the updated ISO-compliant Connecta™ products. Should you require further information or assistance, please do not hesitate to contact your local BD representative.

Sincerely,



Géraldine Comotti-Pfister
EMEA Product Manager – IV Sets
Medication Delivery Solutions