

Transition plan for Cnovate PTCA MDR certificate from MDD certificate

Helix PTCA balloon dilatation catheter and Vecchio PTCA balloon dilatation catheter

Amersfoort, 20, September, 2023 - Today, Cnovate Medical B.V. (hereinafter referred to as "Cnovate") announced that successfully completed the certification process of the European Medical Device Regulation MDR (2017/745) for Helix PTCA balloon dilatation catheter and Vecchio PTCA balloon dilatation catheter, and received European Medical Device Regulation (MDR) certification for these two Class III (highest risk) medical devices.

There are some changes when implementing the new MDR certificate. Cnovate Medical B.V. will actively transfer the new certificates and products, and made a plan for such transition. Please note the current MDD certificates are still valid until 31 December 2027.

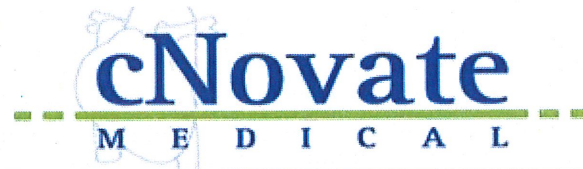
I. The new Helix and Vecchio labelling are listed below:

- 1) Change on new catalog / reference numbers, so as the UDI-DI codes / barcodes
- 2) Change on shelf-life time, from 2 years to 3 years
- 3) Others changes in IFU and labels required by the MDR

The detailed changes please refer to Declaration Letter on Product Labelling Revision from Cnovate Medical.

II. Cnovate medical encourages business partners switching to new certificates and assists in providing documents filing these changes at local DOH. And a transition plan is set as below:

Timeframe	Product availability
01, Oct, 2023 – 31, Dec 2023	Preparation of changes and customer applying for changes at local DOH filing.
01, Jan, 2024 – 30, Mar, 2024	Accept MDR revision orders and start MDR revision sale in EU and others territories. MDD revision are available as well.
01, Apr, 2024 – 31, Mar, 2025	Accept globally MDR revision orders. MDD revision are available as well



01, Apr, 2025 and afterwards	MDR revision orders only
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If there is any question, please feel free to contact your responsible sales manager and email: mariana@cnovate.eu or cs@cnovate.eu.