MedOne®

23 April 2024

Re: MedOne AdvantEdge® Knives – Discontinued CE Mark

Dear Customer,

MedOne is in the process of adopting the new European Medical Device Regulation (MDR), which allows CE marking for devices in Europe. This new regulation has placed a significant burden on medical device manufacturers regarding the technical documentation requirements and subsequent CE certification for their devices.

As part of this transition process to the European MDR, we have been forced to reevaluate our product line. Regrettably, as a result of the associated burden for CE certification the decision has been made to withdraw the AdvantEdge® MVR knives listed below from CE mark certification effective from 26 May 2024.

- 3266 AdvantEdge® MVR Knife 20g
- 3268 AdvantEdge® MVR Knife 23g
- 3269 AdvantEdge® MVR Knife 23g (Angled)
- 3272 AdvantEdge® MVR Knife 23g (Narrow)

The above products will continue to be available to all markets that do not require CE mark certification. As always, these devices remain safe and effective for their intended use. They are being withdrawn from CE mark certification purely due to the costly, excessive and unreasonable burdens of the new MDR regulations, which sadly serve no value to patients or clinicians.

All other MedOne products will continue to be offered with CE marking under MDR as indicated on our manufacturer's declaration regarding our MDR transition.

I apologize for the delayed notice of this change in the CE status of these devices. This was indeed a difficult decision and we regret any inconvenience.

Sincerely,

Bruce Beckstein
President

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