

To whom it may concern

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CONFIRMATION

We,

B. Braun Melsungen AG
Carl-Braun-Str. 1
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Germany

herewith confirm that the medical devices of the following product groups

Infusomat® Space Line
Infusomat® Space Line SafeSet
Infusomat® Plus Line
Infusomat® Plus Line SafeSet
I.V. administration set. For infusion by gravity and compatible pumps

Infusomat® Space Line – Type NRFit
Infusomat® Plus Line – Type NRFit
For Regional Anesthesia only. For application by compatible pumps or gravity.

can be used up to 7 days.

The duration of use is dependent on the intended therapy according to the SPC (Summary of Product Characteristics) of the drug or solution. In general, change of administration sets should occur according national guidelines (e.g. CDC guideline) and / or hospital protocols.

The administration sets should be changed after 96h at the latest in case it is used with an infusion pump.

For and on behalf of

B. Braun Melsungen AG

i. A.


Dr. Meike Junius
Senior Manager Regulatory Affairs
CoE Infusion & Pain Therapy

i. A.


Charlotte Wisker
Administrator Regulatory Affairs International
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