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To whom it may concern

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Enteral Feeding Giving Sets Portfolio: The Giving Sets as the disposable devices from the Enteral Feeding Product Portfolio, are valid for up to 24 hours duration of use and for single use only.

According to MDR 2017/745, Art. 2 (8), "single use" device means a device that is intended to be used on one individual during single procedure". "Single procedure" is not further defined though. This depends on the individual patient situation. Enteral nutrition can be administered with one or a combination of the following methods: continuous, cyclic, intermittent and bolus. It is in the responsibility of the Health Care Professional (HCP) to decide the best feeding method, and how a single procedure would be defined throughout the valid 24 hours duration of use. Against this background, a multiple use during a single procedure within 24 hours is possible.

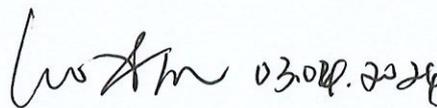
It should be understood that longer enteral feeding duration/ procedure is associated with higher risk of adverse event, e.g. bacterial contamination, degradation of sensitive nutrition, etc. Good Clinical Practice (GCP) should always be ensured. The HCP is responsible to train the lay user on the application of nutrition. Lay users should always consult their HCP in case of any questions.

On behalf of Fresenius Kabi Deutschland GmbH,

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