



Infusion Sets and Infusion Equipment

Intended purpose

Infusion Sets and Infusion Equipment are used for the transport and administration of liquid (e.g. for wound flushing or for Joint lavage). They connect liquid container and / or perfusors with the patient.

Infusion Sets and Infusion Equipment are single used products.

The intended User (attending physician, nurse) have a good expertise in using the Infusion Sets and the Infusion Equipment. Patients and other persons are not allowed to use the Infusion Set and the Infusion Equipment.

Product Classification

According to rule 2:

Products for short-time not invasive use are classified as class IIa product.
(93/42 EWG, Appendix IX, III Classification)

The class IIa classification was made for the following reasons:

The product is for a **short-time use** (continuous application over a period up to 30 days). It can be **connected to an medical device with the class IIa and higher** and it is **not used invasive**. Infusion Sets and Infusion Equipments are used for the **transport and administration of fluids** (e.g. for wound flushing or for Joint lavage).