Curafix® i.v. Soft

REF 33696

May 2022

1. Composition of the product

Curafix® i.v. Soft consists of an adhesive-coated polyester nonwoven on which a wound pad made of a mixture of viscose and PP/PE is placed. The adhesive side is covered with two silicone papers. A loose cushion made of a mixture of viscose and PP/PE is also added to the product.

This product data sheet covers the following item:

REF	Product Description	Feature
33696	Curafix® i.v. Soft	6 x 7,5 cm, sterile

2. Packaging, structure and composition

2.1 Unit Container

1 piece = 1 four-edge sealed pouch
made of cellulose, polyamide and polypropylene

2.2 Shelf Container

50 pieces = 1 folding box of cellulose

2.3 Transit Container

400 pieces (8 folding boxes) = 1 corrugated cardboard box (cellulose)

3. Manufacture

Curafix® i.v. Soft is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.
The product is sterilized by use of ethylene oxide in compliance with DIN EN ISO 11135.

4. Description

Cannula retention dressing made of nonwoven material.

5. Properties

- adheres readily and reliably to the skin
- skin friendly
- good water vapor permeability
- latex free formulation
- dressing leaves little residue when removed
- elastic nonwoven material
- supple
- secure retention

6. Intended purpose

For the fixation of cannulas and catheters on the skin and as a mechanical barrier to protect the puncture site.

7. Medical device classification

Curafix® i.v. Control is a medical devices of class Is according to rule 4.

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of Curafix® i.v. Soft are safe if the product is used appropriately.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device Curafix® i.v. Soft and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Requirements regarding the safety/harmlessness of the constituents

The covering paper has a colophony and colophony derivative content of max. 0,5% critical ingredients.
The polyethylene film of the cushion contains small amounts of tallow-based material of animal origin (125 ppm). The TSE risk from this material is acceptable, because it meets the requirements of ISO 22442-1, Annex C.5.

Currently we do not have further information on critical constituents.

10. Stability

Stored appropriately – dry, protected from dust an light – the material has a shelf life of 3 years from the date of manufacture.

11. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.
Packaging materials must also be disposed of in compliance with applicable national requirements.

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