



Haftan[®] Polyurethane Foam Bandage

REF: 22315 - 22317

October 2022

1. Composition of the product

Haftan[®] Polyurethane Foam Bandage consists of:

- polyurethane foam

The product data sheet is valid for the following items:

REF 22315	Haftan [®] Polyurethane Foam Bandage	7 cm x 27,5 m
REF 22316	Haftan [®] Polyurethane Foam Bandage	10 cm x 27,5 m
REF 22317	Haftan [®] Polyurethane Foam Bandage	10 cm x 27,5 m

2. Packaging, structure and composition

2.1. Unit Container

s. 2.2.

2.2. Shelf Container

- 1 folding box (cellulose)
- cardboard core (cellulose)

REFs	pieces
22315, 22316	6
22317	1

2.3. Transit Container

1 corrugated cardboard case (cellulose):

REFs	pieces	folding boxes
22315, 22316	60	10
22317	40	40

3. Manufacture

Haftan® Polyurethane Foam Bandage is produced according to specification in hygienic conditions and packed according to their packaging specifications.

4. Beschreibung

Haftan® Polyurethane Foam Bandage is a white bandage with good adherence. The bandage is rolled on itself and has a cut bandage end. The bandage is end-fixed.

5. Properties

- thin
- open-pored, supple
- non-bulky
- good adhesion
- white

6. Intended purpose

- for use as a liner for compression and tape bandages
- for the fixation of wound dressings and of padding material under P.o.P. and synthetic casts

7. Medical device classification

Haftan® Polyurethane Foam Bandage is a medical device of Class I according to rule 1 (according to Regulation (EU) 2017/745).

8. Biological evaluation and biocompatibility (DIN EN ISO 10 993)

The starting materials used in the manufacture of Haftan® Polyurethane Foam Bandage are safe if the product is used for the purposes intended.

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 Haftan® Polyurethane Foam Bandage 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 Haftan® Polyurethane Foam Bandage is used under the conditions and for the purposes intended.

9. Requirements regarding the safety/harmlessness of the constituents

According to the supplier's information, there are no ingredients of concern.

10. Stability

Stored appropriately (dry, protected from dust and light), Haftan® Polyurethane Foam Bandage has a shelf life of 3 years from the date of manufacture.

11. Disposal

The user is advised to observe current national legislation, standards, and guidelines regulating the disposal of medical waste.

Packaging materials must also be disposed of in compliance with applicable national requirements.

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Signed by

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