

## Cellona® Synthetic Undercast Padding, unsterile

REF 10686, 10687, 10690, 10692, 10694, 10695, 10696  
 REF 31836 – 31839, 92840 - 92844

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### 1. Composition of the product

Cellona® Synthetic Undercast Padding consists of polyester fibres (PES).

Cellona® Synthetic Undercast Padding can be produced either with Grisuten® 22 3,3 dtex white semi-matt or Trevira® 231 3,3 dtex semi-matt.

This product data sheet covers the following items:

REF	Product Description	Size
10686	Cellona® Synthetic Undercast Padding	6 cm x 3 m
10687		10 cm x 3 m
10690		4 cm x 3 m
10692		6 cm x 3 m
10694		10 cm x 3 m
10695		15 cm x 3 m
10696		20 cm x 3 m
31836		5 cm x 2,7 m
31837		7,5 cm x 2,7 m
31838		10 cm x 2,7 m
31839		15 cm x 2,7m
92840		5 cm x 2,7 m
92841		7,5 cm x 2,7 m
92842		10 cm x 2,7 m
92843		15 cm x 2,7 m
92844		20 cm x 2,7 m

### 2. Packaging, structure and composition

#### 2.1 Unit Container

see 2.2

## 2.2 Shelf Container

1 folding box consisting of cellulose

REF	pieces
10686	6
10687	4

1 LDPE bottom gusseted pouch:

REF	pieces
31836 - 31839	12

## 2.3 Transit Container

1 Wellfaltkiste aus Zellulose

REF	pieces	folding boxes / pouches
10686	60	10 folding boxes
10687	40	10 folding boxes
10690	108	-
10692	72	-
10694	48	-
10695	36	-
10696	24	-
31836	144	12 pouches
31837	72	6 pouches
31838	48	4 pouches
31839	96	8 pouches
92840	96	-
92841	72	-
92842	48	-
92843	36	-
92844	24	-

## 3. Manufacture

Cellona® Synthetic Undercast Padding is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

## 4. Description

Cellona® Synthetic Undercast Padding is a lightly needled, bulk-elastic nonwoven, no optical brighteners. The product is non-sterile.

## 5. Properties

- high-loft, elastic fibrous web
- fibres hold tightly together allowing circular application
- can be gently stretched to become narrower vertically
- air-permeable
- polyester fibre is virtually non-absorbent

## 6. Intended purpose

Cellona® Synthetic Undercast Padding is intended for padding under P.o.P. and synthetic cast and compression bandages.

## 7. Classification

Cellona® Synthetic Undercast Padding is a medical device of class I according to rule 1 (according to directive 93/42/EEC and regulation (EU) 2017/45).

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

The starting materials used in the manufacture of Cellona® Synthetic Undercast Padding 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 Cellona® Synthetic Undercast Padding 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

Currently, we do not have any information on questionable ingredients.

## 10. Stability

Stored appropriately (keep dry, protected from dust and sun) Cellona® Synthetic Undercast Padding has a shelf life of 5 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

Lohmann & Rauscher International GmbH & Co. KG  
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signed by

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Head of Global Marketing