

CELLONA® Synthetic Undercast Padding

REF 10686, 10687, 10690, 10694 – 10697
REF 31836 - 31839, 92840 - 92844

July 2014

Translation: MI / C. Zorn
Revision: MI / M. Fuchs

1. Composition of the product

CELLONA® Synthetic Undercast Padding consists of

- polyester fibres

This product data sheet covers the following items:

REF 10686	Cellona® Synthetic Undercast Padding	6 cm x 3 m	6/60 Stk/SC/TC
REF 10687	Cellona® Synthetic Undercast Padding	10 cm x 3 m	4/40 Stk/SC/TC
REF 10690	Cellona® Synthetic Undercast Padding	4 cm x 3 m	108 Stk/TC
REF 10692	Cellona® Synthetic Undercast Padding	6 cm x 3 m	72 Stk/TC
REF 10694	Cellona® Synthetic Undercast Padding	10 cm x 3 m	48 Stk/TC
REF 10695	Cellona® Synthetic Undercast Padding	15 cm x 3 m	36 Stk/TC
REF 10696	Cellona® Synthetic Undercast Padding	20 cm x 3 m	24 Stk /TC
REF 10697	Cellona® Synthetic Undercast Padding	40 cm x 10 m	1/4 Stk/SC/TC

REF 31836	Cellona® Synthetic Undercast Padding	5 cm x 2,7 m	2 in. x 3 yd.	12/144 Stk/SC/TC
REF 31837	Cellona® Synthetic Undercast Padding	7,5 cm x 2,7 m	3 in. x 3 yd.	12/72 Stk/SC/TC
REF 31838	Cellona® Synthetic Undercast Padding	10 cm x 2,7 m	4 in. x 3 yd.	12/48 Stk/SC/TC
REF 31839	Cellona® Synthetic Undercast Padding	15 cm x 2,7 m	6 in. x 3 yd.	12/96 Stk/SC/TC
REF 92840	Cellona® Synthetic Undercast Padding	5 cm x 2,7 m	2 in. x 3 yd.	96 Stk /TC
REF 92841	Cellona® Synthetic Undercast Padding	7,5 cm x 2,7 m	3 in. x 3 yd.	72 Stk /TC
REF 92842	Cellona® Synthetic Undercast Padding	10 cm x 2,7 m	4 in. x 3 yd.	48 Stk /TC
REF 92843	Cellona® Synthetic Undercast Padding	15 cm x 2,7 m	6 in. x 3 yd.	36 Stk /TC
REF 92844	Cellona® Synthetic Undercast Padding	20 cm x 2,7 m	8 in. x 3 yd.	24 Stk /TC

2. Packaging, structure and composition

2.1 Unit Container

REF 10686, 10687, 10697, 31836 - 31839

- see 2.2

REF 10690, 10692, 10694, 10695, 10696, 92840 - 92844

- see 2.3

2.2 Shelf Container

REF 10686, 10687

- banderole (cellulose)

- cellulose folding box

REF 10697, 31836 - 31839

- banderole (cellulose)

- polyethylene folding box

2.3 Transit Container

REF 10690, 10692, 10694, 10695, 10696, 92840 - 92844

- banderole (cellulose)
- corrugated cardboard box (cellulose)

REF 10686, 10687, 10697, 31836 - 31839

- corrugated cardboard box (cellulose)

3. Manufacture

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

4. Description

White, soft roles in various sizes.

5. Properties

The Synthetic Undercast Padding is a lightly needled, soft and elastic nonwoven with no optical brighteners.

If required, the non-sterile Synthetic Undercast Padding can be sterilized by steam or ethylene oxide according to DIN EN ISO 17665-1 or DIN EN ISO 11135-1, respectively.

6. Intended purpose

CELLONA® Undercast Padding is intended for padding under P.o.P. and synthetic casts and compression bandages.

7. Medical device classification

CELLONA® Undercast Padding is a medical device of class I according to Rule 1, Annex IX of the Council Directive 93/42/EEC concerning medical devices applies

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

The starting material used to produce CELLONA® Undercast Padding is safe provided the product is used appropriately and 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 CELLONA® 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. Stability

Stored appropriately, CELLONA® Undercast Padding has a shelf life of 5 years.

10. 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
D-56579 Rengsdorf
signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)