



medical[®]
leather

a healthy focus on feet

Product Specific Information Document

Product name:	Leukoplast
Item code:	LE P125, LE P25, LE P5, CO 04, CO 06, CO 08, HA S19, HA S30
Barcode:	N.A.
CE Marking:	N.A.
MDR Risk Classification:	Riskclass I

Product summary:	Leukoplast
Size / Contents product:	multiple
Packaging size:	per roll
Packaging unit:	per roll
Color:	white
Thickness:	N/A
Shorevalue:	N/A
Implementation:	N/A
Storage advise:	Out of the sun
Maintenance advise:	N/A
Sterilisation advise:	N/A
Manufacturing date:	N/A
Shelf life:	See packaging

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Website www.medical-leather.nl Rabobank 1308.95.377 • BIC Code RABONL2U • IBAN nr. NL63 RABO 0130 8953 77 •
KVK 18124129 • BTW nr. NL8145 15 745 B01



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DECLARATION OF CONFORMITY

The undersigned

C.J. Maas – Leder LEFA BV. / Medical Leather

In reference

To the REACH Regulation 1907/2006/CE

Concerning the Registration, Evaluation, Authorization

And the restriction of chemical substances

DECLARES THAT

- Our company purchases and sells foam sheets through the transformation of polymers, mineral fillers, pigments and chemicals. Therefore, as a user, our company is not bound to any registration
- According to the REACH Regulation polymers are exempted from registration (article 2) as well as most of the raw materials used.
- Through the raw material suppliers and sheet suppliers, we were able to ascertain compliance with the REACH legislation. In fact, the chemical manufacturers, where provided, have taken steps as for regular registration.
- With regard to the presence of hazardous substances (SVHC) mentioned in **the last list published by ECHA on 25/06/2020** we declare that our products, after curing, as supplied by us, has no hint of SVHC in a concentration above the threshold limit of 0.1%..

Pieve del Cairo, 22/07/2020

REACH Responsible

Pieter Maas

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We,

**Medical Leather
Zanddonkweg 6
5144 NX Waalwijk
The Netherlands**

hereby declare under our own responsibility, that this product family complies with the applicable regulations of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product Name:

Leukoplast® soft white

Basic UDI-DI:

4042809400329489E

Intended purpose:

For minor wounds like cuts, lacerations, abrasions or as cover of puncture sites after blood withdrawal or vaccination.

Conformity assessment route: **Annex II+III**

Classification rule: **4**

Classification: **I**

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

Date of Issue: 03.11.2021

Article	Description	REF
76450-00003-00	LEUKOPLAST SOFT WHITE 19X72MM 100 DE DA EN FI FR IT NL NO PT SV ES	76450-03
76450-00004-00	LEUKOPLAST SOFT WHITE 38X72MM 100 DE DA EN FI FR IT NL NO PT SV ES	76450-04
76450-00012-00	LEUKOPLAST SOFT WHITE 12 19MX72MM, 8 38X72MM 1 IT PT ES (20DRS 2SIZES)	76450-12
76450-00013-00	LEUKOPLAST SOFT WHITE 12 19MX72MM, 8 38X72MM 1 NL FR DE IT CENTRAL (20DRS 2SIZES)	76450-13
76450-00014-00	LEUKOPLAST SOFT WHITE 12 19MX72MM, 8 38X72MM 1 DA EN FI NO SV NORDIC (20DRS 2SIZES)	76450-14
76450-00015-00	LEUKOPLAST SOFT WHITE 38X72MM 10 IT PT ES	76450-15
76450-00016-00	LEUKOPLAST SOFT WHITE 38X72MM 10 NL FR DE	76450-16
76450-00017-00	LEUKOPLAST SOFT WHITE 38X72MM 10 EN FI SV	76450-17
76450-00018-00	LEUKOPLAST SOFT WHITE 19X72MM 20 IT PT ES	76450-18
76450-00019-00	LEUKOPLAST SOFT WHITE 19X72MM 20 EN FI SV	76450-19
76450-00020-00	LEUKOPLAST SOFT WHITE 16 19MX72MM, 10 D22MM, 6 38X38MM, 8 38X72MM 1 IT PT ES (40DRS 4SIZES)	76450-20
76450-00021-00	LEUKOPLAST SOFT WHITE 12 19X72MM, 6 D22MM, 8 38X72MM, 4 38X38MM 1 NL FR DE IT CENTRAL (30DRS 4SIZES)	76450-21
76450-00022-00	LEUKOPLAST SOFT WHITE 12 19X72MM, 6 D22MM, 8 38X72MM, 4 38X38MM 1 DA EN FI NO SV NORDIC (30DRS 4SIZES)	76450-22
76450-00023-00	LEUKOPLAST SOFT WHITE 38X38MM 1000 DE DA EN FI FR IT NL NO PT SV ES	76450-23
76450-00024-00	LEUKOPLAST SOFT WHITE 19X72MM 1000 DE DA EN FI FR IT NL NO PT SV ES	76450-24
76450-00025-00	LEUKOPLAST SOFT WHITE 38X72MM 1000 DE DA EN FI FR IT NL NO PT SV ES	76450-25
76450-00028-00	LEUKOPLAST SOFT WHITE 19X72MM 20	76450-28