



medical<sup>®</sup>  
leather

a healthy focus on feet

## Product Specific Information Document

<b>Product name:</b>	<b>Evalux E</b>
Item code:	EV E
Barcode:	N/A
CE Marking:	N/A
MDR Risk Classification:	Riskclass I
Product summary:	Evalux E
Size / Contents product:	85 x 65 cm
Packaging size:	plate, cutted shapes
Packaging unit:	per plate
Color:	white
Thickness:	2, 3, 4, 5, 6, 8 en 10 mm
Shorevalue:	60 ShoreA
Implementation:	N/A
Storage advise:	not in direct sunlight
Maintenance advise:	N/A
Sterilisation advise:	N/A
Manufacturing date:	N/A
Shelf life:	N/A

**Postbus 95, 5140 AB Waalwijk • Zanddonkweg 6, 5144 NX Waalwijk • The Netherlands**

**Telefoon** +31 (0)416 37 69 87 • **Fax** +31(0)416 37 56 02 • **E-mail** info@medical-leather.nl •

**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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date last revision 28/02/2020

## SAFETY DATA SHEET

### 1- PRODUCT AND COMPANY IDENTIFICATION DETAILS

- 1.1 Product name: **ML-CAD 40-50-60 shore**
- 1.2 PRODUCER: CMP SRL- Via Matteotti 52-27037 Pieve Del Cairo (PV)
- 1.1 Company phone number for urgent calls: 0384-831772

### 2- INGREDIENT/COMPOSITION INFORMATION

SUBSTANCE	N.CAS	
E.V.A. (ethylene/vinyl acetate)	24937-78-8	
Calcium carbonate	471-34-1	
Silicon dioxide	7631-86-9	
Stearic acid	67701-03-5	
Zinc oxide	1314-13-2	
Peroxide	25155-25-3	
Azodicarbonamide	123-77-3	
Zinc stearate	91051-01-3	
Styrene butadiene rubber	9003-55-8	
For the colors, they are used various combinations of the following materials:		
Organic pigments	//	
Yellow iron oxide	51274-00-1	
Red iron oxide	1309-37-1	
Brown iron oxide	//	
Black iron oxide	1317-61-9	
Bitumen	//	
Titanium dioxide	13463-67-7	
Carbon black	1333-86-4	

### 3. DANGER IDENTIFICATION

- 3.1 Main health risks:  
No specific danger has been found in normal use
- 3.2 Main risks for the environment  
Not to be disposed in the environment

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#### **4. FIRST- AIO MEASURES**

- 4.1 Skin contact: no particular procedure

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#### **5. FIRE PREVENTION MEASURES**

- 5.1 Recommended extinguishers : Atom ised water , C02, Plastic foam, Chemical powder, Halons.
- 5.2 Forbidden extinguishers : None
- 5.3 Combustion risks: The vapours produced by thermal decomposition may irritate the skin and mucal areas. Avoid breathing the fumes .
- 5.4 Protection means: Protective clothing complete with autorespiration system

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#### **6. MEASURES INTHE EVEN OFACCIDENTAL LEAKAG**

Not verifiable

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#### **7. HANDLING ANO STORAG**

- 7.1 Handling: Handling of the material at room temperature is risk-free:
- 7.2 Storage: away from sunlight , in well-aired places that are not excessively hot
- 7.3 Precautions : avoid open flames, place the equipment on the floor to avoid accumulating static electricity .

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#### **8. EXPOSURE /INDIVIDUAL PROTECTION CHECKS**

- 8.1 Precautions: Adequatel ventilate the premises in which the product is stored.
- 8.2 Respiratory protection: Not necessary
- 8.3 Eye protection: Not necessary
- 8.4 Exposure limits of the substances making up the sam : none

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## 9. CHEMICAL AND PHYSICAL PROPERTIES

- 9.1 Physical state: solid- Available in sheets from 60x120 cm to 120x190 cm, thickness varies from 2 to 40 mm
- 9.2 Colour: available in various colours
- 9.3 Odour: n. a.
- 9.4 pH: n. a.
- 9.5 Density: from 0.15 g/cm<sup>3</sup> to 1.20 g/cm<sup>3</sup> based on the articles
- 9.6 Inflammability : n. a.

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## 10. STABILITY AND REACTIVITY

- 10.1 The product is stable and chemically inert at room temperature.

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## 11. TOXICOLOGICAL INFORMATION

- 11.1 This product is not toxic. However, in the event of fire, the fumes that may develop may irritate the respiratory system.

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## 12. ECOLOGICAL INFORMATION

- 12.1 The product is not biodegradable. It does not contain additives based on lead, mercury, cadmium and hexavalent chrome. It does not present risks for the water table.  
USE THE PRODUCT ACCORDING TO GOOD WORKING PRACTICE AND  
DISPOSE OF THE PRODUCT IN AN ENVIRONMENTALLY FRIENDLY  
WAY AFTER USE.

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## 13. DISPOSAL CONSIDERATIONS

- 13.1 Proceed in accordance with current local and national regulations.



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## 14. TRANSPORT INFORMATION

- 14.1 This product is not considered dangerous goods.

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## 15. REGULATORY INFORMATION

- 15.1 In accordance with D.M. 28/1/92 L-D, this product is not considered dangerous goods.
- 15.2 Where applicable, reference should be made to the following regulations:  
D.P.R. 303/56 (sanitary checks)- circulars no. 46/79 and 61/81 -Ministry of Labour.  
D.P.R. 175/88 (Seveso Directive), Enclosure 2°, 3° and 4°.

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## 16. FURTHER INFORMATION

- 16.1 Main bibliographic sources: safety sheet for the substances used in the manufacture of this product  
The above information is based on our knowledge on the date indicated above. It refers solely to the product indicated and does not constitute a guarantee of any special qualities. The user must make sure that the information is suitable and complete in relation to the intended use.  
This fact sheet annuls and replaces all previous editions.

## TECHNICAL DATA SHEET

<b>ARTICLE</b> <b>050</b> <b>name: EVASOFT</b>	<b>COLOR</b> <b>Z097</b>	<b>FINISHING BLOCK</b> <b>roughed on both sides</b>
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<b>DIMENTION SHEET*</b> <b>not trimmed mm 1050x1600</b>	<b>THICKNESS</b> from mm 3,0 to mm 40,0
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Basic polymer	E.V.A . (ethylene vinyl acetate)
Cellular structure	closed
Hardness Shore A din53505	50/55 shore A
Specific Weight (Kg/m3)	250
Compression set Din53517 (72h 21° 25% 30')	residual deformation 11% of the initial thickness
Cytotoxicity test MOR (Medical Oevice Regulation) EN ISO10993/5	compliant cellular vitality >70% )

**\*dimensional tolerance+/-5%**