



medical<sup>®</sup>  
leather

a healthy focus on feet

## Product Specific Information Document

**Product name:** Silicona duo  
**Item code:** SI DU30  
**Barcode:** N/A  
**CE Marking:** N/A  
**MDR Risk Classification:** Riskclass I

**Product summary:** Silicona duo  
**Size / Contents product:** 2x 250 gram  
**Packaging size:** 2 potten  
**Packaging unit:** per set  
**Color:** various  
**Thickness:** N/A  
**Shorevalue:** 30 ShoreA  
**Implementation:** N/A  
**Storage advise:** cool, dark place, not in direct sunlight  
**Maintenance advise:** A finished orthosis can be washed with a pH-neutral soap  
**Sterilisation advise:** This product can/does not have to be steralized  
**Manufacturing date:** N/A  
**Shelf life:** see packaging

**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



medical  
leather®

a healthy focus on feet

## 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

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](mailto:info@medical-leather.nl) •

Website [www.medical-leather.nl](http://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



# DECLARACION UE DE CONFORMIDAD EU DECLARATION OF CONFORMITY

**FABRICANTE:** FRESCO INTERNATIONAL 2005, S.A.  
**MANUFACTURER:**

**DIRECCIÓN:** Pol. Ind. Can Volart  
**ADDRESS:** C/Torre de Cellers 5, naves 3 y 4  
08150 Parets del Vallés, Barcelona, España

**DECLARARA BAJO SU EXCLUSIVA RESPONSABILIDAD, QUE EL PRODUCTO(S):  
DECLARE UNDER THEIR SOLE RESPONSIBILITY, THAT THE PRODUCT(S):**

**UDI-DI básico:** 84350579F-01922VA  
**Basic UDI-DI:**

**Nombre comercial:** Silicona orthesil  
**Trade name:** *Silicone orthesil*

**Referencia:** F-01922  
**Reference:**

**Tipo:** Ayudas técnicas  
**Type:** *Technical aids*

**Clase de riesgo:** Dispositivo médico de Clase I  
**Risk class:** *Medical device Class I*

**CUMPLE(N) LOS REQUISITOS DEL REGLAMENTO:  
MEETS(S) THE REQUIREMENTS OF THE REGULATION:**

2017/745/EC Sobre los productos sanitarios  
*On medical devices*

**RESPETA(N) EL SEGUIMIENTO DE LAS NORMAS APLICABLES:  
RESPECT(S) THE MONITORING OF THE APPLICABLE STANDARDS:**

ISO 9001:2015  
ISO13485:2016

  
FRESCO INTERNATIONAL 2005, S.A.  
N.I.F. A63702633  
Pol. Ind. Can Volart  
C/ Torre de Cellers, 5, naves 3 y 4  
08150 Parets del Vallés (Barcelona)  
Tel. 93 573 94 00

**Lugar/Place:** Barcelona  
**Fecha/Date:** 19/04/2021

**Aitor Fresco**  
Director General  
General Director