



medical[®]
leather

a healthy focus on feet

Product Specific Information Document

Product name: **Silicona Fresco**

Item code: SI SIFR

Barcode: N/A

CE Marking: N/A

MDR Risk Classification: Riskclass I

Product summary: Silicona Fresco

Size / Contents product: 500 gram

Packaging size: pot

Packaging unit: per stuk

Color: rose

Thickness: N/A

Shorevalue: 14-16 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 •

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



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