



Polichem S.A.  
Registered Office:  
50, Val Fleuri,  
L-1526 Luxembourg  
Tel. +352-26864924  
Fax. +352-26864925  
Reg. B n° 57.059  
VAT n° LU 16989482

Mendrisio – Branch  
Via Angelo Maspoli, 11  
6850 Mendrisio  
Switzerland  
Tel. +41-91-9864000  
Fax +41-91-9864001  
e-mail: info.polichem@almirall.com

## DECLARATION OF CONFORMITY

We, the undersigned **POLICHEM S.A.** Via Angelo Maspoli, 11, 6850 Mendrisio, Switzerland, as manufacturer according to Directive 93/42/CEE of the medical devices in object, whose EC authorized representative is Almirall S.A., General Mitre, 151, 08022 Barcelona, Spain hereby

### DECLARE

that the following product:

#### **TANNO-HERMAL® cream**

GMDN code: 60306 – inflammatory skin disorder dressing

(see **Annex 5 list for codes, brand names and countries**)

classified as a **class IIa** medical device according to Rule 4 of Annex IX of the 93/42/EEC Directive, and subsequent amendments and upgrades, has been manufactured in accordance with the technical documentation required in 93/42/EEC Directive, annex VII, point 3, and satisfies the Essential Requirements defined in 93/42/EEC Directive, annex I, as amended.

We also declare that the CE marking of **Tanno-Hermal® cream** has been applied according to:

EC Declaration of conformity (full quality assurance), according to Annex II, excluding point 4, of 93/42/EEC Directive and subsequent amendments and upgrades.

*Ref. CE Certificate n. EPT 0477. MDD.20/3857 by:*

#### **Eurofins Products Testing Italy srl**

Via Cuorgnè 21, 10156 Torino – ITALY

Notified Body n° : 0477

Validity of the Certificate: January 21<sup>st</sup> 2024<sup>(1)</sup>

(1) Polichem SA is allowed to place Tanno-Hermal® cream on the market until 31 December 2028 based on the above mentioned CE Certificate because is in compliance with all the conditions listed in Article 120.3c of MDR, as amended by Regulation (EU) 2023/607, as stated in the confirmation letter (Reference 23Q07262 Rev.01 COVER.0) issued on 20/12/2023 by Eurofins Products Testing Italy srl.

We further declare that procedures for post-marketing surveillance and product traceability applies.

This document was electronically signed in eDMS R&D system, in Mendrisio, by the PRRC of Polichem SA. Manifestation of the e-signature is available at the end of this document which are the equivalent of handwritten signature, in compliance with 21CFR Part 11.

**TF-18-11-01-Letter DOC\_FEB 2024**

**ELECTRONIC SIGNATURES**

<b>Signed by</b>	<b>Meaning of Signature</b>	<b>Server Date</b> <small>(dd-MMM-yyyy HH:mm 'GMT'Z)</small>
Juan Francisco Raya Cortes	Management Approval	26-Feb-2024 07:47 GMT+0

**eDMS R&D Object\_ID:** 09000075805293f4

**List of CE marked product codes**

The following codes are covered by the “Declaration of CE Conformity” in accordance to Annex 11:

<b>SAP CODE</b>	<b>DESCRIPTION</b>	<b>COUNTRY</b>	<b>DISTRIBUTOR</b>	<b>SHIPMENT INSTRUCCIONES (1)</b>	<b>NOTES</b>
4905235	Tanno-Hermal cream 50 g	Austria	Almirall GmbH	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	Shared pack AT/CH
60003891	Tanno-Hermal cream 20 g	Poland	Almirall Sp. z o.o.	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	
60003892	Tanno-Hermal cream 50 g				
4905235	Tanno-Hermal cream 50 g	Switzerland	Almirall AG	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	Shared pack AT/CH

(1) Euro pallets; material wood

# TF-18-05-Product codes\_rev\_04\_NOV 2023

## ELECTRONIC SIGNATURES

<b>Signed by</b>	<b>Meaning of Signature</b>	<b>Server Date</b> (dd-MMM-yyyy HH:mm 'GMT'Z)
Francesc Xavier Binefa Rodriguez	Quality Assurance Approval	03-Nov-2023 14:05 GMT+0
Javier Segado Ferran	Regulatory Affairs Approval	06-Nov-2023 12:13 GMT+0
Juan Francisco Raya Cortes	Management Approval	06-Nov-2023 15:09 GMT+0

**eDMS R&D Object\_ID:** 090000758050557e