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## 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® lotio

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® lotio* 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.20/3858 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® lotio 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-15-11-01-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

**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 INSTRUCCIONS</b>	<b>NOTES</b>
4903744 <sup>(1)</sup>	Tanno-Hermal Lotio 100 g	Belgium	Almirall N.V.	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	
4903741 <sup>(1)</sup>	Tanno-Hermal Lotio 100 g	Czech & Slovak Republic	Not available (consignment stock)	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	
4903743 <sup>(1)</sup>	Tanno-Hermal Lozione 100 g	Italy	Almirall S.p.A	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	
4903740 <sup>(1)</sup>	Tanno-Hermal Lotio 100 g	Poland	Almirall Sp. z.o.o.	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	
4904090 <sup>(1)</sup>	Tanno-Hermal Lotio 100 g	Switzerland	Almirall AG	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	

(1) Manufacturing site: Almirall Hermal GmbH

# TF-15-05-Product codes\_rev\_02\_NOV 2022

## ELECTRONIC SIGNATURES

<b>Signed by</b>	<b>Meaning of Signature</b>	<b>Server Date</b> (dd-MMM-yyyy HH:mm 'GMT'Z)
Javier Segado Ferran	Regulatory Affairs Approval	03-Nov-2022 18:12 GMT+0
Francesc Xavier Binefa Rodriguez	Quality Assurance Approval	04-Nov-2022 09:02 GMT+0
Juan Francisco Raya Cortes	Management Approval	04-Nov-2022 11:14 GMT+0

**eDMS R&D Object\_ID:** 0900007580488123