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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:

ECOCEL® hydrosoluble nail lacquer  
(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/CEE Directive, and subsequent amendments and upgrades, has been manufactured in accordance with the technical documentation required in 93/42/CEE Directive, annex VII, point 3, and satisfies the Essential Requirements defined in 93/42/CEE Directive, annex I, as amended.

We also declare that the CE marking of *Ecocel® hydrosoluble nail lacquer* 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.19/3110 by:

Eurofins Products Testing Italy srl  
Via Cuornè 21, 10156 Torino – ITALY  
Notified Body n° : 0477

Validity of the Certificate: February 3th, 2024

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

This document was electronically signed in eDMS R&D system by an authorized Proxy 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-05-11-Letter\_DOC JUN 2021**

**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	15-Jun-2021 08:11 GMT+02

**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</b>	<b>NOTES</b>
60006041 (1)	Ecocel 3.3 ml sale	Italy	Difa Cooper S.p.A.	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (cap “a profilo quadrato” and brush) supplied by Bisio Progetti - ref. Annex 15
60006002 (1)	Sililevo 3.3 ml sale	Germany	Almirall Hermal GmbH	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (100 white cap and brush) supplied by Bisio Progetti – Ref. annex 15
60006001 (1)	Sililevo 6.6 ml sale				
60007283 (1)	Sililevo 1.65 ml sample				
60007550 (1)	Betalfatrus 3.3 ml sale	Spain	Almirall S.A.	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (100 white cap and brush) supplied by Bisio Progetti - ref. Annex 15
60007651 (1)	Betalfatrus 1.65 ml sample				
60007223 (1)	Betalfatrus 3.3 ml sale	Portugal	Almirall Produtos Farmacêuticos, Lda	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (cap “a profilo quadrato” and brush) supplied by Bisio Progetti - ref. Annex 15
60006524 (1) 60005578 (2)	Kitolac 3.3 ml sale	Austria	Almirall GmbH	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (cap “a profilo quadrato” and brush) supplied by Bisio Progetti - ref. Annex 15

<b>SAP CODE</b>	<b>DESCRIPTION</b>	<b>COUNTRY</b>	<b>DISTRIBUTOR</b>	<b>SHIPMENT INSTRUCCIONS</b>	<b>NOTES</b>
60006042 (1) 60005294 (2)	Psoriatec 3.3 ml	France, Belgium	Laboratoires Bailleul S.A.	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (cap “a profilo quadrato” and brush) supplied by Bisio Progetti - ref. Annex 15
60006526 (1) 60005437 (2)	Kloril P 3.3 ml sale	Switzerland	Almirall AG	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (100 white cap and brush) supplied by Bisio Progetti – Ref. annex 15
60006527 (1) 60005173 (2)	Kloril P 1.5 ml sample				
60006530 (1)	Sililevo Nail Lacquer 3.3 ml	Hungary, Slovak Rep.	Angelini Pharma	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (cap “a profilo quadrato” and brush) supplied by Bisio Progetti - ref. Annex 15
60007760 (1)	Sililevo Nail Lacquer 3.3 ml	Greece	Galenica S.A.	ROAD Controlled Temperature (+15° / +25° C) ADR LQ	Primary packaging (cap “a profilo quadrato” and brush) supplied by Bisio Progetti - ref. Annex 15

(1) Almirall Hermal GmbH

(2) Sinerga

**List of non-CE marked product codes**

The following codes are listed here for “easiness of handling” towards the third party manufacturer. However, they are not covered by the “Declaration of CE Conformity” in accordance to Annex 11; they are not listed in Mod. 26 “Elenco Dispositivi”; they are not released according to the procedure for Mod. 30:

SAP CODE	DESCRIPTION	COUNTRY	DISTRIBUTOR	SHIPMENT INSTRUCCIONES*	NOTES
60006562 (1) 60005313 (2)	Sililevo 3.3 ml sale	Paraguay	Farmedis Paraguay	AIR Controlled Temperature (+15° / +25° C) DGR ID8000	Cosmetic class 3 according to local regulation  Primary packaging (100 white cap and brush) supplied by Bisio Progetti – Ref. annex 15

(1) Almirall Hermal GmbH

(2) Sinerga

# TF-05-05-Product codes\_rev\_31\_JUN 2021

## ELECTRONIC SIGNATURES

<b>Signed by</b>	<b>Meaning of Signature</b>	<b>Server Date</b> (dd-MMM-yyyy HH:mm 'GMT'Z)
Merixell Fornes Dordal	Regulatory Affairs Approval	03-Jun-2021 14:44 GMT+02
Francesc Xavier Binefa Rodriguez	Quality Assurance Approval	07-Jun-2021 10:45 GMT+02
Juan Francisco Raya Cortes	Management Approval	08-Jun-2021 07:27 GMT+02