



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:

ECOCEL® hydrosoluble nail lacquer

GMDN code: 47918 – nail infection solution

(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 Cuorgnè 21, 10156 Torino – ITALY
Notified Body n° : 0477

Validity of the Certificate: February 3th, 2024⁽¹⁾

(1) Polichem SA is allowed to place Ecocel® 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-05-11-01-Letter DOC_FEB 2024

ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date <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:

SAP CODE	DESCRIPTION	COUNTRY	DISTRIBUTOR	SHIPMENT INSTRUCCIONES	NOTES
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)	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

SAP CODE	DESCRIPTION	COUNTRY	DISTRIBUTOR	SHIPMENT INSTRUCTIONS	NOTES
60006042 (1)	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)	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)	Kloril P 1.5 ml sample				
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

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
60007180 (1)	Betalfatrus 3.3 ml sale	Mexico	Italmex	AIR Controlled Temperature (+15° / +25° C) DGR ID8000	
60007181 (1)	Betalfatrus 1.65 ml sample				

(1) Sinerga

TF-05-05-Product codes_rev_35_APR 2022

ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date <small>(dd-MMM-yyyy HH:mm 'GMT'Z)</small>
Merixell Fornes Dordal	Regulatory Affairs Approval	19-Apr-2022 18:10 GMT+0
Francesc Xavier Binefa Rodriguez	Quality Assurance Approval	20-Apr-2022 10:01 GMT+0
Juan Francisco Raya Cortes	Management Approval	20-Apr-2022 10:33 GMT+0