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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:

JACUTIN PEDICUL® FLUID

GMDN code: 49982 – lice treatment solution, synthetic

(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 **Jacutin Pedicul® fluid** 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.20/3854 by:

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

Validity of the Certificate: January 21st 2024⁽¹⁾

(1) Polichem SA is allowed to place Jacutin Pedicul® 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-20-11-01-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

TECHNICAL DOCUMENTATION N. 20

JACUTIN PEDICUL® FLUID

Annex n° 05:
Product Codes

POLICHEM S.A.

Via Angelo Maspoli 11
6850 Mendrisio
Switzerland

Rev.	Reasons for revision:	Prepared by	Reviewed and verified by	Approved by	Date
06	Elimination SKU 60006650 for Jacutin Pedicul 200 ml DE because the comb is inserted inside the box instead of sleeved outside the box with a plastic wrap. Minor editorial changes.	RA	QA	MR	
See electronic signatures and dates in last page					
05	Update according to “List of SKUs vs Manufacturing sites (SRD-0009254)”: - Deletion of Almirall Hermal GmbH: no active manufacturing site				11.01.2021
04	Addition of intermediate SAP codes manufactured for the presentation of 200 ml in Germany (4905247 in Almirall Hermal GmbH and 60006259 in IFA SAB). These codes are converted into 4905248 and 60006650, respectively, after the comb had been sleeved externally to the packs.				01.07.2020
03	Updates SAP codes presentations for Germany (Almirall Hermal GmbH and IFA SA)				15.10.2019
02	Insert details of the presentations containing comb and where is located (inside or outside the pack). Discontinuation of product in Hungary				21.06.2019
01	First release (transfer legal manufacturer responsibilities from Almirall Hermal GmbH to Polichem SA)				26.04.2019

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 (1)	NOTES
60006251 (2)	Pedicul Hermal 100 ml	Austria	Almirall GmbH	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	Contains comb inside the pack.
60006250 (2)	Pedicul Hermal 200 ml				Common pack AT/CH
60006254 (2)	Pedicul Hermal 100 ml	Czech Republic	NA	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	Contains comb inside the pack. Common pack CZ/SK
60006258 (2)	Jacutin Pedicul 100 ml	Germany / Luxembourg	Almirall Hermal GmbH	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	Doesn't contain comb.
60006259 (2)	Jacutin Pedicul 200 ml				Contains comb inside the pack.
60006278 (2)	Pedicul Hermal 100 ml	Poland	Almirall Sp. z o.o.	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	Contains comb inside the pack.

SAP CODE	DESCRIPTION	COUNTRY	DISTRIBUTOR	SHIPMENT INSTRUCCIONS (1)	NOTES
60006254 (2)	Pedicul Hermal 100 ml	Slovak Republic	NA	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	Contains comb inside the pack. Common pack CZ/SK
60006251 (2)	Pedicul Hermal 100 ml	Switzerland	Almirall AG	Road transport; Controlled Temperature (+15° / +25° C) not dangerous goods	Contains comb inside the pack.
60006250 (2)	Pedicul Hermal 200 ml				Common pack AT/CH

(1) Euro pallets; material wood

(2) Industrias Farmacéuticas Almirall S.A., Sant Andreu de la Barca

TF-20-05-Product codes_rev_6_JUN 2021

ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date (dd-MMM-yyyy HH:mm 'GMT'Z)
Javier Segado Ferran	Regulatory Affairs Approval	25-Jun-2021 13:30 GMT+02
Francesc Xavier Binefa Rodriguez	Quality Assurance Approval	28-Jun-2021 09:44 GMT+02
Juan Francisco Raya Cortes	Management Approval	28-Jun-2021 11:24 GMT+02