



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:

JACUTIN PEDICUL® FLUID

(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 Cuorgnè 21, 10156 Torino – ITALY

Notified Body n° : 0477

Validity of the Certificate: January 21st 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-20-11-Letter_DoC JUN 2021

ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date <small>(dd-MMM-yyyy HH:mm 'GMT'Z)</small>
Juan Francisco Raya Cortes	Management Approval	15-Jun-2021 08:28 GMT+02

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 <small>(dd-MMM-yyyy HH:mm 'GMT'Z)</small>
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