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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:

GYNOMUNAL® vaginal gel and its applicator

GMDN Code: 47899 – vaginal mucosa protecting dressing

(see Annex 5 list for codes, brand names and countries)

classified as a class IIa medical device according to Rule 5 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 *Gynomunal® vaginal gel* 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. 19/3107 by:

Eurofins Product 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 Gynomunal® 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-04-11-01-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
60006384 (1)	Gynomunal vaginal gel 15 ml - sample	Germany	Almirall Hermal GmbH	TIR: ROAD Controlled temperature +15°C-+ 25°C Not dangerous goods	the box contains 1 applicator shared pack with Austria
60006383 (1)	Gynomunal vaginal gel 50 ml - sale				
60006475 (1)	Rosalтроf vaginal gel 15 ml - sample	Spain	Angelini Spain	TIR: ROAD Controlled temperature +15°C-+25°C Not dangerous goods	the box contains 1 applicator
60006150 (1)	Rosalтроf vaginal gel 50 ml - sale				the box contains 10 applicators
60006384 (1)	Gynomunal vaginal gel 15 ml - sample	Austria	Almirall GmbH	TIR: ROAD Controlled temperature +15°C-+25°C Not dangerous goods	the box contains 1 applicator shared pack with Germany
60006383 (1)	Gynomunal vaginal gel 50 ml - sale				
60006470 (1)	Gynomunal vaginal gel 50 ml - sale	Israel	Megapharm	TIR: AIR Controlled temperature +15°C-+ 25°C Not dangerous goods	the box contains 1 applicator
60006471 (1)	Gynomunal vaginal gel 15 ml - sample				the box contains 1 applicator

SAP CODE	DESCRIPTION	COUNTRY	DISTRIBUTOR	SHIPMENT INSTRUCTIONS	NOTES
60006478 (1)	Gynomunal vaginal gel 50 ml - sale	Sweden	Erol AB	TIR: ROAD Controlled temperature +15°C-+ 25°C Not dangerous goods	the box contains 1 applicator
60006479 (1)	Gynomunal vaginal gel 15 ml - sample				
60006480 (1)	Gynomunal vaginal gel 50 ml - sale	UK – Switzerland	Cederberg GmbH	TIR: ROAD Controlled temperature +15°C-+ 25°C Not dangerous goods	the box contains 5 applicators
60006481 (1)	Gynomunal vaginal gel 15 ml - sample				the box contains 1 applicator

(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

SAP CODE	DESCRIPTION	COUNTRY	DISTRIBUTOR	SHIPMENT INSTRUCCIONES	NOTES
60005127 (2)	Gynatrof gel 15 ml sample	Canada	Tyros Biopharma Inc	TIR: AIR Controlled temperature +15°C-+25°C Not dangerous goods	the box contains 1 applicator
60005128 (2)	Gynatrof gel 50 ml sale				
60007762 (2)	Gynatrof 15 ml sample	US	Tyros Biopharma Inc	TIR: AIR Controlled temperature +15°C-+25°C Not dangerous goods	the box contains 1 applicator
60006850 (2)	Gynatrof 50 ml sale				
60006473 (1)	Gynomunal vaginal gel 15 ml - sample	Mexico	IFA (Investigacion Farmacéutica S.A de C.V.)	TIR: AIR Controlled temperature +15°C-+ 25°C Not dangerous goods	the box contains 1 applicator Expiry date on the 15 ml and 50 ml tubes should be indicated in the following format [mm]-[yyyy] No additional digits "d" after the batch number on the secondary packaging should be indicated. The pallets should be protected by angle brackets
60006472 (1)	Gynomunal vaginal gel 50 ml - sale				

(1) Almirall Hermal GmbH; (2) Biokosmes

TF-04-05-Product codes_rev_29_JAN 2023

ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Date (dd-MMM-yyyy HH:mm 'GMT'Z)
Francesc Xavier Binefa Rodriguez	Quality Assurance Approval	31-Jan-2023 12:57 GMT+01
Javier Segado Ferran	Regulatory Affairs Approval	08-Feb-2023 12:33 GMT+0
Juan Francisco Raya Cortes	Management Approval	08-Feb-2023 12:57 GMT+0