Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. _____din _____

Solicitantul Pharmony S.R.L., cu sediul în mun.Chișinău, or.Durlești, str.Durlești, 4, tel: 0 696 46 604, 0 799 844 01, e-mail info@pharmony.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr.	Denumire	Modelul	Nr. catalog	Tara	Producător
1	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 250ml	SSP2025U	Franța	MACO PHARMA
2	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 280ml	SSP2028U	Franța	MACO PHARMA
3	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 300ml	SSP2030U	Franța	MACO PHARMA
4	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 280ml	SSP2128U	Franța	MACO PHARMA
5	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 300ml	SSP2130U	Franța	MACO PHARMA
6	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 500ml	SSP2150U	Franța	MACO PHARMA

Se anexează următoarele acte:
1. Scrisoarea de autorizare de la producător;
2. Declarația de conformitate CE;
3. Certificat de conformitate CE;
4. Declarația pe proprie răspundere;

Alexandru Șarco
Director Semnătura _____

Tabelul de recepționare a notificării

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Digitally signed by Șarco Alexandru Date: 2023.11.17 15:26:28 EET Reason: MoldSign Signature Location: Moldova
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitivelor Medicale

DECLARATIE PE PROPRIE RĂSPUNDERE

Solicitant: Pharmony SRL, cu sediul în mun.Chișinău, or.Durlești, str. Durlești, 4,

declar pe proprie răspundere, cunoscând prevederile **art.352[1],** Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea următoarelor dispozitive medicale:

Nr.	Denumire	Modelul	Nr. catalog	Tara	Producător
1	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 250ml	SSP2025U	Franța	MACO PHARMA
2	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 280ml	SSP2028U	Franța	MACO PHARMA
3	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 300ml	SSP2030U	Franța	MACO PHARMA
4	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 280ml	SSP2128U	Franța	MACO PHARMA
5	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 300ml	SSP2130U	Franța	MACO PHARMA
6	Soluție aditivă pentru trombocite	Platelet additive solution SSP+, 500ml	SSP2150U	Franța	MACO PHARMA

Sunt autentice și corespund realității.

Alexandru Șarco
Director

Semnătura _____

Data

Tourcoing, 18th October 2023,

Letter of Authorization

We,

Macopharma,

Located at Rue Lorthiois – 59420 Mouvaux – France, as the manufacturer of platelets additive solution, including all the articles mentioned in the Declaration of Conformity attached to this submission, hereby authorize **Pharmony S.R.L.** – 4, Durlesti Str., Chisinau, MD2071, Republic of Moldova to prepare and submit applications for the evaluation and registration of the abovementioned medical devices to the Competent Authorities on our behalf.

This authorisation shall remain in effect until our notification to the Competent Authorities in writing (either by postal mail, e-mail or facsimile transmission) that it is revoked – subject to any conditions imposed by the Competent Authorities.

We undertake to provide all the necessary support and assistance to the representative as may be required in relation to any matter involving the above mentioned medical devices.

We agree to provide and assist the competent authorities with any request for information on the above mentioned medical devices.

The authorisation is valid for one year.

Ludovic Kotewicz

Area Manager EEME

MACOPHARMA
RUE LORTHIOIS
59420 MOUVAUX
TEL. : 03.20.11.85.55
FAX : 06.66.72.02.07

macopharma

Déclaration CE de Conformité
EC Declaration of Conformity

Nous / *we*,

MACO PHARMA
Rue Lorthiois
59420 MOUVAUX
FRANCE

Déclarons, conformément à la Directive 93/42/CEE amendée par la Directive 2007/47/CE, Annexe IX, que les dispositifs médicaux :

Solution de conservation de plaquettes SSP+

sont classés en Classe III, en application de la règle 13,

Declare, according to the Directive 93/42/EEC amended by the 2007/47/EC Directive, Annex IX, that the medical devices:

Storage solution for platelets SSP+

are in Class III, according to the rule 13,

Déclarons que lesdits dispositifs sont conformes aux exigences essentielles de la Directive 93/42/CEE amendée par la Directive 2007/47/CE, Annexe I,
Declare that the aforementioned devices comply with the essential requirements of the Directive 93/42/EEC amended by the Directive 2007/47/EC, Annex I,

Déclarons que la procédure d'évaluation de la conformité a été établie conformément à la Directive 93/42/CEE amendée par la Directive 2007/47/CE, Annexe II, points 3 et 4,
Declare that the procedure of conformity assessment has been established to conform to the Directive 93/42/EEC amended by the Directive 2007/47/EC, Annex II, sections 3 and 4,

Mouvaux, le / *on : 29/10/2021*

Au nom du fabricant, / *On behalf of the manufacturer,*

Nom / *Name* : Raouf BENYAMINA

Personne qualifiée / *Qualified person : Responsable Affaires Réglementaire / Regulatory Affairs Manager*

Cette Déclaration de Conformité CE est associée au certificat de marquage CE N° 10389 rev.7, délivré par l'organisme notifié G-Med (1, rue Gaston Boissier, 75015 Paris) N°0459 , valable jusqu'au 26 Mai 2024, et au certificat de marquage CE N° 20330 rev.6 valable jusqu'au 26 Mai 2024.

This EC Declaration of Conformity is linked to the CE-Mark Certificate N° 10389 rev.7, issued by the Notified Body G-Med (1, rue Gaston Boissier, 75015 Paris)N°0459 valid until May 26th 2024 and to the CE-Mark certificate N° 20330 rev.6, also issued by the GMed, valid until May 26th 2024.

Rue Lorthiois - 59420 Mouvaux – Tél. : 03 20 11 84 30 – Télécopie : 03 20 11 84 86

Liste des références couvertes par la déclaration CE « Solution de conservation de plaquettes SSP+ »
List of references covered by the EC declaration "Storage solution for platelets SSP+"

Désignation du dispositif médical *Medical device designation*	**Référence du dispositif médical** *Medical device reference*	**Classe du dispositif médical** *Medical device class*
Solution de conservation de plaquettes SSP+ *Storage solution for platelets SSP+*	SSP2020U	III
	SSP2022U	
	SSP2025U	
	SSP2028U	
	SSP2030U	
	SSP2030O	
	SSP2128U	
	SSP2130U	
	SSP2150U	
	SSP2150A	
	SSP2150O	

Mouvaux, le / *on* 29/10/2021
Au nom du fabricant, / *On behalf of the manufacturer,*

Responsable Affaires Réglementaires / *Regulatory Affairs Manager*

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 10389 rev. 7**
Délivrée à Paris le 18 novembre 2020
Issued in Paris on November 18th, 2020

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

MACO PHARMA
Rue Lorthiois
59420 MOUVAUX FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Solutions de conservation de plaquettes sanguines

Blood platelet storage solutions

Voir document complémentaire GMED / See GMED additional document
n° 37504

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P181089 - P601303, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P181089 - P601303, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **November 18th, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

DocuSigned by:
Béatrice LYS
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GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

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GMED - 10389 rev. 7
Annule et remplace le certificat 10389-6

Délivré à Paris le 21/10/2021
Issued in Paris on 10/21/2021

Ce document complémentaire GMED n° 37504 rev. 1 atteste de la validité du certificat CE n° 10389 rev. 7 au regard des informations listées ci-dessous.

This GMED additional document n° 37504 rev. 1 attests to the validity of CE certificate n° 10389 rev. 7 with regard to the information listed below.

Fabricant / *Manufacturer:*

MACO PHARMA
Rue Lorthiois
59420 MOUVAUX FRANCE

Identification des dispositifs / *Identification of devices*

Désignation du dispositif *Medical Device designation*	**Référence du dispositif médical** *Medical Device reference*	**Classe du DM** *MD Class*	**Code GMDN** *GMDN code*
Solution de conservation des plaquettes SSP + *Storage solution for platelets SSP +*	**SSP2020U**	**III**	**47125**
	SSP2022U		
	SSP2025U		
	SSP2028U		
	SSP2030U		
	SSP2030O		
	SSP2128U		
	SSP2130U		
	SSP2150U		
	SSP2150A		
	SSP2150O		

GMED 0459

GMED – 37504 rev. 1
Modifie le document n° 37504 rev. 0

DocuSigned by:
Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director

Sites couverts et Activités / *Locations and Activities*

Sites / *Locations*	**Activités** / *Activities*
Maco Pharma - Rue Lorthiois - 59420 Mouvaux – France	**Siège social – Responsable de la mise sur le marché /** *Headquarters – Legal manufacturer*
Maco Productions – 200 Chaussée Fernand Forest – 59200 Tourcoing – France **Maco Productions – Rue Lorthiois – 59420 Mouvaux – France**	**Conception – Fabrication – Distribution /** *Design – Manufacture – Distribution*
Maco Productions Polonia – Sp. Z.o.o. ul Szwajcarska – 54405 Wroclaw – Pologne	**Fabrication – Distribution /** *Manufacture - Distribution*
MACO MD - Lot 99 - Zone industrielle Chotrana 2- 2056- Raoued – Ariana - Tunisie	**Fabrication – Distribution /** *Manufacture - Distribution*

Modifications / *Modifications*

Identification des modifications apportées au certificat CE n° 10389 rev. 7:
Identification of the modifications made to the CE certificate n° 10389 rev. 7:

Modifications / *Modifications*	**Dossier(s)** / *File(s)* **N°**	**Date** / *Date*
Mise à jour de la liste de références *Update of list of refereces*	**NA**	**21/10/2021** *10/21/2021*

GMED	0459

GMED – 37504 rev. 1
Modifie le document n° 37504 rev. 0

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DocuSigned by:
Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 20330 rev. 6**
Délivrée à Paris le 18 novembre 2020
Issued in Paris on November 18th, 2020

ATTESTATION CE / *EC CERTIFICATE*

Examen CE de la Conception (du produit) / EC Design Examination (of the product)
ANNEXE II point 4 de la directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II section 4 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / *Manufacturer*

MACO PHARMA
Rue Lorthiois
59420 MOUVAUX FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Solution de conservation de plaquettes

Storage solution for platelets

Identification du(des) dispositif(s) / *Identification of device(s)*

SSP+

SSP+

Voir document complémentaire GMED / See GMED additional document
n° 37503

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P602256-1, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file(s) referenced P602256-1, the product(s) complie(s) with the requirements of the directive 93/42/EEC, annex 1

Début de validité / *Effective date :* **November 18th, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

DocuSigned by:
Béatrice LYS
GMED SAS
GMED
GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED - 20330 rev. 6
Renouvelle le certificat 20330-5

GMED_b2p4_new2020-V0-04-2020

Délivré à Paris le 18/10/2021
Issued in Paris on 10/18/2021

Ce document complémentaire GMED n° 37503 rev. 1 atteste de la validité du certificat CE n° 20330 rev. 6 au regard des informations listées ci-dessous.

This GMED additional document n° 37503 rev. 1 attests to the validity of CE certificate n° 20330 rev. 6 with regard to the information listed below.

Fabricant / *Manufacturer:*

MACO PHARMA
Rue Lorthiois
59420 MOUVAUX FRANCE

Identification des dispositifs / *Identification of devices*

Désignation du dispositif *Medical Device designation*	**Référence du dispositif médical** *Medical Device reference*	**Classe du DM** *MD Class*	**Code GMDN** *GMDN code*
Solution de conservation des plaquettes SSP + *Storage solution for platelets SSP +*	**SSP2020U**	**III**	**47125**
	SSP2022U		
	SSP2025U		
	SSP2028U		
	SSP2030U		
	SSP2030O		
	SSP2128U		
	SSP2130U		
	SSP2150U		
	SSP2150A		
	SSP2150O		

GMED 0459

GMED - 37503 rev. 1
Modifie le document n° 37503 rev. 0

GMED SAS GMED SAS
DocuSigned by:
Béatrice LYS
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Modifications / *Modifications*

Identification des modifications apportées au certificat CE n° 20330 rev. 6:
Identification of the modifications made to the CE certificate n° 20330 rev. 6:

Modifications / *Modifications*	**Dossier(s)** / *File(s)* **N°**	**Date** / *Date*
Mise à jour de la liste de références *Update of list of refereces*	**NA**	**18/10/2021** *10/18/2021*

GMED	0459

GMED - 37503 rev. 1
Modifie le document n° 37503 rev. 0

DocuSigned by:
Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director