Către Agenţia Medicamentului şi Dispozitivelor Medicale

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

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 826**, e-mail: **tatiana.grecu@dita.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 producătorului **Pharmplast S.A.E., Egypt :**

- Pansament ocular adeziv steril Cure Aid Eye Pad
- Emplastru pentru fixarea cateterelor steril Pharmapore IV 6x7cm
- Pansament adeziv steril Pharmapore 10x30cm
- Pansament adeziv steril Pharmapore 10x10cm
- Pansament adeziv steril Pharmapore 5x7cm
- Pansament adeziv steril Pharmapore 8,2x20cm
- Pansament adeziv steril Pharmapore 8,2x35cm

Se anexează următoarele acte:
- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Certificat de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale (format Excel).

Data **13.09.2023** Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Moraru Grigore
Date: 2023.09.17 11:00:32 EEST
Reason: MoldSign Signature
Location: Moldova

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producatorului producătorului **Pharmplast S.A.E., Egypt:**

- Pansament ocular adeziv steril Cure Aid Eye Pad
- Emplastru pentru fixarea cateterelor steril Pharmapore IV 6x7cm
- Pansament adeziv steril Pharmapore 10x30cm
- Pansament adeziv steril Pharmapore 10x10cm
- Pansament adeziv steril Pharmapore 5x7cm
- Pansament adeziv steril Pharmapore 8,2x20cm
- Pansament adeziv steril Pharmapore 8,2x35cm

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia:

Semnătura _____

Data ***13.09.2023***

Pharmaplast

We, Pharmaplast S.A.E., Alexandria, Egypt,

based in **Amria free zone 23512, Alexandria, Egypt**, **assign Dita Estfarm LLC**, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as **authorized representative** in correspondence with the conditions of Regulation (EU) 93/42.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Alexandria, Egypt

Date: 04.01.2022

Signed: Dina Desouki

PHARMA PLAST S.A.E
ALEXANDRIA - EGYPT

S.R.L. "DITA ESTFARM" IDNO 1002600046359

Pharmaplast S.A.E
Amria free zone 23512
Tel: 002034500264
Fax: 002034500263
Website: www.pharmaplast-online.com
Email: sales@pharmaplast-online.com

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 27237 rev. 8**
Délivrée à Paris le 13 avril 2021
Issued in Paris on April 13th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système d'assurance Qualité de la Production (limitée à l'obtention et au maintien de l'état stérile)
Approval of Production Quality Assurance System (related to securing and maintening sterile conditions)
ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / *Manufacturer*

PHARMAPLAST SAE
Amria Free Zone, 23512
ALEXANDRIA EGYPT

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

Pansements absorbants stériles, non adhésifs stériles, pansements stériles utilisés en premiers soins, champs opératoires stériles, bandes adhésives stériles pour fermetures de plaies et bandes adhésives stériles pour fixation de cathéters

Absorbent, non-adherent sterile dressing, Sterile wound dressings, Sterile First Aid dressings, Sterile theatre incise drapes, Sterile skin closure strips and Sterile catheter securement dressings

Voir document complémentaire GMED / See GMED additional document
n° 38017

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001042, le système d'assurance qualité - pour l'obtention et le maintien de l'état stérile - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T001042, the quality system - for the quality system for securing and maintaining sterile conditions - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex V section 3.

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 :* **February 17th, 2021 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, MUN. CHIȘINĂU, 18 "DITA ESTFARM" S.R.L. IDNO 1002600046359

GMED SAS GMED GROUPE LNE GMED SAS

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

GMED - 27237 rev. 8
Annule et remplace le certificat 27237-7

GMED_bSs_new2020-V0-04-2020

GMED
GROUPE LNE

Document complémentaire GMED n° 38017 rev. 1
GMED additional document n° 38017 rev. 1
Dossier(s) / *File(s)* N° T001042

Délivré à Paris le 13/04/2021
Issued in Paris on 04/13/2021

Ce document complémentaire GMED n° 38017 rev. 1 atteste de la validité du certificat CE n° 27237 rev. 8 au regard des informations listées ci-dessous.

This GMED additional document N° 38017 rev. 1 attests to the validity of CE certificate n° 27237 rev. 8 with regard to the information listed below.

Fabricant / *Manufacturer:*

Pharmaplast SAE
Amria Free Zone,
Alexandria, Egypt, 23512

Identification des dispositifs / *Identification of devices*

Description du Dispositif Médical *Medical Device Description*	**Référence Commerciale du Dispositif Médical** *Medical Device Commercial Reference Number*	**Classe du Dispositif Médical** *Medical Device Class*
Absorbent non-adherent Sterile dressing	Vilowond pad Vilowond carbon Vilowond carbon plus Vilowond plus	I(s)
Post-operative dressings with silicone low adherent wound contact layer	Pharmapore Gentle Pharmapore PU Gentle Pharmapore PU Gentle Frame style Pharmapore Ultra Gentle Pharmapore IV Gentle Pharmapore PU IV Gentle Pharmapore PU IV Gentle Frame style Protectfilm Gentle Protectfilm Gentle Frame style	
Adhesive plasters with silicone	Cure-Aid Gentle	

S.R.L. "DITA ESTFARM" IDNO 1002600046359

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

GMED 0459

GMED - 38017 rev. 1

On behalf of the President
Béatrice LYS
Technical Director

Sterile wound dressings	Pharmapore Pharmapore PU Pharmapore IV Pharmapore PU IV Pharmapad Phrampad Carbon Protectfilm FlexAgrip™ Catheter Securement Device Pharmapore® Catheter Securement Dressing Pharmapore® PU IV Frame Style with FlexAgrip™ Vilowond® Gauze Vilowond® Nonwoven Gauza Plus	I(s)
Sterile first Aid dressings	Cure-Aid	
Sterile theatre incise drapes	Incifilm General Surgery Pharma-Drape Universal Set Super I Universal Set I Universal Set II Laparoscopy Set I Laparoscopy Set II Minor Surgery Set Universal Paediatrics Set Gynecology Surgery : Gynecology Set I Gynecology Set II Gynecology / Cystoscopy Set I Obstetrics surgery : Caesarean Section Set II Caesarean Section Set III Orthopedics Surgery : Shoulder Arthroscopy Set I Arthroscopy Set I Arthroscopy Set II Hip Set I Hip Set II Extremity Set I Extremity Set II Vertical Isolation Set I Hand Set Hand / Foot Set I Spinal Set	I(s)

SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA S.R.L. "DITA ESTFARM" IDNO 1002600046359 CHIȘINĂU 18

GMED 0459

GMED - 38017 rev. 1

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Sterile theatre incise drapes	ENT and Maxillofacial Surgery: ENT Set I Urology Surgery : Urology Set I Cardiothoracic Surgery : Cardiovascular Set I Cardiovascular Surgery : Angiography Set I Angiography Set II Neurosurgery Surgery : Neurosurgery Set I Pharma-Drape Sheets : Pharma-Drape PE film Pharma-Drape Bi-laminate Pharma-Drape Tri-laminate Pharma-Drape Adhesive	I(s)
Sterile skin closure strips	Pharmastrip Pharmastrip fabric	I(s)
Sterile catheter securement dressings	Absoclear cushion rings Absoclear cushion tracheostomy Absoclear IV dressings	

Sites couverts et Activités / *Locations and Activities*

Sites / *Locations*	**Activités** / *Activities*
Pharmaplast S.A.E. Amria Free Zone Alexandria, 23512, Egypt	**Fabrication et contrôle final /** *Manufacturing and final control*
Bulgaria Site KRE LTD, Industrial area Katunsi Sandanski 2830, Bulgaria	**Fabrication et contrôle final /** *Manufacturing and final control*
Borg El Arab Part number 2, block 7, third industrial zone, Borg el Arab, Alexandria, Egypt	**Fabrication et contrôle final /** *Manufacturing and final control*

S.R.L. "DITA ESTFARM" IDNO 1002600046359 SOCIETATE CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, mun. CHIȘINĂU

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

GMED 0459

GMED - 38017 rev. 1

On behalf of the President
Béatrice LYS
Technical Director

Pharmaplast

DECLARATION OF CONFORMITY

We

MANUFACTURER'S NAME:
Pharmaplast SAE
MANUFACTURER'S ADDRESS:
Amria free zone 23512,
Alexandria, Egypt

AUTHORIZED REPRESENTATIVE'S NAME:
E C Rep Ltd,
AUTHORIZED REPRESENTATIVE'S ADDRESS:
5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland.
Tel: +353 1 2 544 944
Email: info@ecrep.ie

Declare that the product covered by this declaration is in compliance with requirements of the Annex I of the directive 93/42/EEC, as amended by 2007/47/EC, and are manufactured and placed in the market under the sole responsibility of the manufacturer following the regulations of this directive.

Product information:
Name: Cure-Aid®
Indications: Cure Aid® and dressing strip®:: Intended for the protection of minor acute wounds such as cuts, skin scratches, abrasions, lacerations and after blood drawing or vaccination.
Cure Aid® Blue Metal & X-ray Detectable plasters and dressing strip®: Ideal to cover minor wounds, abrasions, superficial wounds and skin cuts in food processing factories, restaurants,...etc.
Cure Aid® Eye pad: Intended for patients with minor eye injuries, foreign objects embedded in their eyes and with lazy eye disorder. Besides, the pad can be used after eye trauma e.g. corneal abrasion and may provide initial protection from possible risk of infection.
Code: Annex 1: Table of sizes and codes
Size: Annex1: Table of sizes and codes
GMDNs code: 34864
Applicable standards: Annex 2: List of applicable standards

Classification:
The products Cure-Aid® are classified as a Short term (continuous use for not more than 30 days) non-invasive devices according to Annex IX rule 4, of MDD 93/42/EEC, as amended by 2007/47/EC as class I sterile Medical device.
Conformity assessment procedure: in accordance with Annex V of MDD 93/42/EEC as amended by 2007/47/EC.

Notified body information:
Name: GMED SAS
Address: 1, rue Gaston Boissier 75015 Paris France
Identification Number: 0459
Certificate no. : 27237

Regulatory Affairs Department	Signature	Place	Date	Version
Ereny Nashaat	Ereny Nashaat	Alexandria, Egypt	22-Dec-20	08

Company Stamp

PHARMA PLAST S.A.E
ALEXANDRIA-EGYPT

SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, mun. CHIȘINĂU
S.R.L.
"DITA ESTFARM"
IDNO 1002600046359
SOCIETATEA 18

Change History:

Version Number	Date	Change	Rationale for Change
2	01-Nov-18	updated DoC form & SOP updated DoC form version(2) Addition of "Indication", addition of "Version" and adding certification no. Addition of clarification of MDD reference. Addition of UMDNS code.	For better compliance with ISO 13485:2016. Requested from SGS audit. For sections to be well defined and changing of company letter-head.
3	1-11-2018	Addition of Cure Aid® Eye pad and Blue Metal Detectable plasters indications	Adding the rest of family to be included in the same DoC, to be aligned with the technical file.
4	05-02-2019	Change EC/Rep and the related information.	Due to Brexit issues, change of Authorized representative
5	14-07-2019	updated DoC form version (3) Change notified body and the related information. Indications rephrasing. Change GMDN code. Documenting annex 1 to be template (TM/RA/001-1) and annex 2 to be template (TM/RA/001-2) updated DoC form version(4) Adding change history table.	Transfer of some files to GMED notified body. To be aligned with updated CER and technical file. To document these annexes. To control DoC changes.
6	18-09-2019	Adding dressing strip to annex 1 and DoC. Amend annex 2.	To cover whole range in one declaration. Remove some irrelevant test standards.
7	02/11/2019	Amend annex 2	To be comply with applicable standard.
8	22/12/2020	Adding missing sizes. Amend annex 2.	Amend mistake. To be comply with applicable standard.

Annex 1
Table of sizes and codes

Version no:	04	Date:	22/12/2020

Cure-Aid® Adhesive Plaster	Size (mm)	Size (Inch)	Pieces/Box	Boxes/Case
CURE938	9 X 38 mm	0.35 X 1.5 in	100	60
CURE1657	16 X 57 mm	0.63 X 2.24 in	100	60
CURE1938	19 X 38 mm	0.75 X 1.5 in	100	60
CURE1963	19 X 63 mm	0.75 X 2.48 in	100	60
CURE1964	19 X 64 mm	0.75 X 2.52 in	100	60
CURE1972	19 X 72 mm	0.75 X 2.83 in	100	60
CURE1976	19 X 76 mm	0.75 X 2.99 in	100	60
CURE2572	25 X 72 mm	0.98 X 2.83 in	100	60
CURE2576	25 X 76 mm	0.98 X 2.99 in	100	60
CURE3055	30 X 55 mm	1.18 X 2.17 in	100	60
CURE3064	30 X 64 mm	1.18 X 2.52 in	100	60
CURE3072	30 X 72 mm	1.18 x 2.83 in	50	60
CUREANCHOR	30 X 72 mm Anchor	1.18 x 2.84 in	50	60
CURE3838	38 X 38 mm	1.5 X 1.5 in	100	60
CURE3872	38 X 72 mm	1.5 X 2.83 in	50	60
CURE5072	50 X 72 mm	1.97 X 2.83 in	50	60
CURE50100	50 X 100 mm	2 X 4 in	50	60
CURE5060	50 X 60 mm Fingertip	1.97 X 2.36 in	50	60
CURE4563	45 X 63 mm Butterfly	1.77 X 2.48 in	50	60
CURE25	SPOT 25 mm	0.98 in	100	192
CURE22	SPOT 22 mm	0.8 in	100	192
CURE2525	25 X 25 mm	0.98 X 0.98 in	100	60
EYEPAD5062	50x62 mm Eyepad child	Eyepad child	20	40
EYEPAD5882	58x82 mm Eyepad Adult	Eyepad Adult	20	40
EYEPAD6595	65x95 mm Ocular	Ocular	20	40
CUREFEET	Feet	Feet	10	48
CURE2235	22 x 35 mm	0.9 x 1.4 in	100	60
CURE2665	26 x 65 mm	1.5 x 2.6 in	100	60
CURE3070	30 x 70 mm	1.18 x 2.8 in	100	60
CURE64110	64 X 110 mm OVALADULT	2.5 x 4.3 in	50	60
CURE5284	52 X 84 mm OVALCHILD	2.04 x 3.3 in	50	60
CURE20120	20 x 120 mm	0.8 x 4.7 in	100	60
CURE30120	30 x 120 mm	1.2 x 4.7 in	100	60
CURE20180	20 x 180 mm	0.8 x 7 in	100	60

Annex 1
Table of sizes and codes

CURE30180	30 x 180 mm	1.2 x 7 in	100	60
CURE2582	25 x 82 mm	1 x 3.2 in	100	60
CURE2956	29 x 56 mm	1.1 x 2.2 in	100	60
CURECHARACTERS	19x63 mm	0.75 X 2.48 in	100	60
CURE1955	19 x 55 mm	0.7 x 2.2 in	100	60
CURE4550	45 x 50 mm Butterfly	1.8 x 2.2 in	50	60

Cure-Aid® Dermi plaster	Size (mm)	Size (Inch)	Pieces/Box	Boxes/Case
DERMI60100	60 x 100 mm	2.4 x 4 in	10	48
DERMI601000	60 x 1000 mm	2.4 x 39.4 in	1	48
DERMI80100	80 X 100 mm	3.1 x 4 in	10	120
DERMI801000	80 x 1000 mm	3.1 x 39.4 in	1	120
DERMI40100	40 x 100 mm	1.57 x 4 in	10	120
DERMI60200	60 x 200 mm	2.4 x 7.87 in	10	120
DERMI2560	25 x 60 mm	0.98 x 2.4 in	100	60
DERMI401000	40 x 1000 mm	1.57 x 39.4 in	1	120
DERMI40500	40 x 500 mm	1.57 x 19.69 in	1	120
DERMI60500	60 x 500 mm	2.4 x 19.69 in	1	120
DERMI80500	80 x 500 mm	3.15 x 19.69 in	1	120
DERMI20120	20 x 120 mm	0.8 x 4.7 in	100	60
DERMI30120	30 x 120 mm	1.18 x 4.7 in	100	60
DERMI20180	20 x 180 mm	0.8 x 7 in	100	60
DERMI30180	30 x 180 mm	1.18 x 7 in	100	60
DERMI20120IW	20 x 120 mm	0.8 x 4.7 in	100	60
DERMI30120IW	30 x 120 mm	1.18 x 4.7 in	100	60
DERMI20180IW	20 x 180 mm	0.8 x 7 in	100	60
DERMI30180IW	30 x 180 mm	1.18 x 7 in	100	60

PHARMA PLAST S.A.E
ALEXANDRIA - EGYPT

SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA
S.R.L.
"DITA ESTFARM"
IDNO 1002600046359
CHIȘINĂU 18

ANNEX 2
List of applicable standards

Version no:	02	Date:	10/01/2019

EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes.
DIN EN ISO 14971: 2012	Medical devices – Application of risk management to medical devices
EN ISO 10993 1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for cytotoxicity: in vitro methods.
DIN EN ISO 10993-10:2014	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
EN ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials.
ISO 11135-1: 2014 / Amd 1:2018	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of sterilization process for medical devices.
EN ISO 14161:2009	Sterilization of healthcare products – Biological indicators – Guidance for selection, use and interpretation of results
EN ISO 11737-1: 2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
ISO 15223-1: 2016	Symbols to be used with medical device labels, labelling and information to be supplied.
BS EN 1041: 2008 + A1:2013	Information supplied by the manufacturer with medical devices.
BS EN ISO 11607: 2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems Part 2: Validation requirements for forming, sealing and assembly processes.
MEDDEV 2.4/1: Rev. 9, 06.2010	Guidelines for the Classification of Medical Devices.
MEDDEV 2.7.1: Rev 4, 06.2016	Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies.
ISO 14644	Clean room and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015); Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015) Part 3: Test methods (ISO 14644-3:2005) Part 4: Design, construction and startup (ISO 14644-4:2001)

ANNEX 2
List of applicable standards

	Part 5: Operations (ISO 14644-5:2004) Part 7: Separated devices (clean air hoods, glove boxes, isolators and mini-environments) (ISO 14644-7:2004)
IEC 62366-1: 2015	Medical devices -- Part 1: Application of usability engineering to medical devices.
ASTM F 1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO 2859-1: 1999	Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
BS EN 868-5:2018	Standard Test Method for Seal Strength of Flexible Barrier Materials.
ASTM F1929:2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
BS EN 13726-2: 2002	Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings.
FINAT 12	Determination of Weight measurement
DIN 13019: 2016	Adhesives for first aid – Dimensions.
Finat 9	Loop Tack Test
AFERA 5001, Finat 1	Measurement of Peel Adhesion From Stainless Steel
AFERA 5001	Measurement of Peel Adhesive from Stainless Steel or from its Own Backing
ISO 13726 -1:2002	Test methods for primary wound dressings. Aspects of absorbency
ASTM D 1777-96:2007	Standard Test Method for Thickness of Textile Materials

Pharmaplast

DECLARATION OF CONFORMITY

We

MANUFACTURER'S NAME:
Pharmaplast SAE
MANUFACTURER'S ADDRESS:
Amria free zone 23512,
Alexandria, Egypt

AUTHORIZED REPRESENTATIVE'S NAME:
E C Rep Ltd,
AUTHORIZED REPRESENTATIVE'S ADDRESS:
5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland.
Tel: +353 1 2 544 944
Email: info@ecrep.ie

Declare that the product covered by this declaration is in compliance with requirements of the Annex I of the directive 93/42/EEC, as amended by 2007/47/EC, and are manufactured and placed in the market under the sole responsibility of the manufacturer following the regulations of this directive.

Product information:
Name: Pharmapore® Family (Pharmapore, Pharmapore PU, Pharmapore I.V., Pharmapore PU I.V.)
Indications: Post-operative Dressings: Primary dressings indicated for low to moderate exuding wounds such as minor cuts, abrasions, lacerations and puncture sites. Besides, they can be used post-operatively to protect surgical wounds and incisions. **I.V. Dressings:** The I.V. variants are used for catheter and cannula fixation and securement.
Code: Annex 1: Table of sizes and codes
Size: Annex1: Table of sizes and codes
GMDN code: 58301, 56631 and 34864.
Applicable standards: Annex 2: List of applicable standards

Classification:
The products **Pharmapore® Family** are classified as a Short term (continuous use for not more than 30 days) non-invasive devices according to Annex IX rule 4, of MDD 93/42/EEC, as amended by 2007/47/EC as class I Sterile Medical device.
Conformity assessment procedure: in accordance with Annex V of MDD 93/42/EEC as amended by 2007/47/EC.

Notified body information:
Name: GMED SAS
Address: 1, rue Gaston Boissier 75015 Paris France.
Identification Number: 0459
Certificate no. : 27237

Regulatory Affairs Department	Signature	Place	Date	Version
Ereny Nashaat	Ereny Nashaat	Alexandria, Egypt	12.01.2023	14

Pharmaplast

Company Stamp

PHARMA PLAST S.A.E
ALEXANDRIA - EGYPT

Change History:

Version Number	Date	Change	Rationale for Change
02	17/12/2018	Updated DoC form version (2) Addition of "Indications" Addition of "Version" Addition of "certification no." Addition of clarification of MDD reference. Addition of UMDNS code.	For sections to be well defined and changing of company letter head. Requested changes from SGS audit. For better compliance with ISO 13485:2016
03	13/07/2019	Updated DoC form version (3) Change of EC/Rep and notified body related information. Indications rephrasing and change of GMDN code. Documenting annex 1 to be template (TM/RA/001-1) and annex 2 to be template (TM/RA/001-2) Updated DoC form version (4) Adding change history table.	Due to Brexit issues, change of Authorized representative. Transfer of some files to GMED notified body. Update of technical file and Clinical Evaluation. To document these annexes. To control DoC changes.
04	05/11/2019	New version of Annex 1 (Ver.02)	Amending typo
05	08/12/2019	New version of Annex 1 (Ver.03)	Adding a missing code
06	02/06/2020	Updated version of Annex 1 (Ver.04) Updated version of Annex 2 (Ver.02)	Customer request to add new packaging configuration according to CRS. To comply with latest updated legal standards.

07	**25/06/2020**	Updated version of Annex 2 (Ver.03)	To be in compliance with Legislative References as per its latest update.
08	**22/12/2020**	Update Annex I Update Annex II	Customer request to add new packaging configuration according to CRS. To be in compliance with Legislative References as per its latest update.
09	**11/03/2021**	Update Annex II	To be aligned with NHS requirements.
10	**28/04/2021**	Amend Annex I	File maintenance
11	**04/09/2021**	Amend Annex I	File maintenance
12	**16/10/2021**	Amend Annex I by amending size and its related code	Amending typo to maintain the file
13	**08.09.2022**	Amend Annex I	File maintenance
14	**12.01.2023**	Amend Annex I	File maintenance

Annex 1
Table of sizes and codes

Version no:	10	Date:	12/01/2023

Pharmapore	Pharmapore Ultra	Pharmapore PU	Pharmapore PU Frame Style	Size	Pieces/Box	Boxes/Case
PORE5070	POREU5070	POREPU5070	POREPUFS5070	5x7cm	200	8
PORE6070	POREU6070	POREPU6070	POREPUFS6070	6x7cm	200	8
PORE6080	POREU6080	POREPU6080	POREPUFS6080	6x8cm	200	8
					150	8
PORE5090	POREU5090	POREPU5090	POREPUFS5090	5x9cm	200	8
PORE6083	POREU6083	POREPU6083	POREPUFS6083	6x8.3cm	200	8
PORE50100	POREU50100	POREPU50100	POREPUFS50100	5x10cm	200	8
PORE6082	POREU6082	POREPU6082	POREPUFS6082	6x8.25cm	200	8
PORE6085	POREU6085	POREPU6085	POREPUFS6085	6x8.5cm	200	8
PORE7080	POREU7080	POREPU7080	POREPUFS7080	7x8cm	200	8
PORE6580	POREU6580	POREPU6580	POREPUFS6580	6.5x8cm	200	8
PORE7575	POREU7575	POREPU7575	POREPUFS7575	7.5x7.5cm	200	8
PORE6090	POREU6090	POREPU6090	POREPUFS6090	6x9cm	200	8
PORE60100	POREU60100	POREPU60100	POREPUFS60100	6x10cm	200	8
PORE5082	POREU5082	POREPU5082	POREPUFS5082	5x8.25cm	200	8
PORE75100	POREU75100	POREPU75100	POREPUFS75100	7.5x10cm	100	8
PORE80100	POREU80100	POREPU80100	POREPUFS80100	8x10cm	100	8
PORE82100	POREU82100	POREPU82100	POREPUFS82100	8.25x10cm	100	8
PORE100100	POREU100100	POREPU100100	POREPUFS100100	10x10cm	100	8
PORE70120	POREU70120	POREPU70120	POREPUFS70120	7x12cm	60	8
PORE80120	POREU80120	POREPU80120	POREPUFS80120	8x12cm	60	8
PORE100120	POREU100120	POREPU100120	POREPUFS100120	10x12cm	60	8
PORE125125	POREU125125	POREPU125125	POREPUFS125125	12.5x12.5cm	10	24
PORE83120	POREU83120	POREPU83120	POREPUFS83120	8.3x12cm	60	8
PORE90150	POREU90150	POREPU90150	POREPUFS90150	9x15cm	10	24
					60	8
PORE80150	POREU80150	POREPU80150	POREPUFS80150	8x15cm	60	8
PORE82150	POREU82150	POREPU82150	POREPUFS82150	8.25x15cm	60	8
PORE100140	POREU100140	POREPU100140	POREPUFS100140	10x14cm	60	8
PORE100150	POREU100150	POREPU100150	POREPUFS100150	10x15cm	60	8
PORE83180	POREU83180	POREPU83180	POREPUFS83180	8.3x18cm	60	8
PORE82200	POREU82200	POREPU82200	POREPUFS82200	8.25x20cm	40	8
PORE90200	POREU90200	POREPU90200	POREPUFS90200	9x20cm	10	24
					40	8
PORE100200	POREU100200	POREPU100200	POREPUFS100200	10x20cm	40	8
PORE83240	POREU83240	POREPU83240	POREPUFS83240	8.3x24cm	40	8
PORE82250	POREU82250	POREPU82250	POREPUFS82250	8.25x25cm	40	8
PORE90250	POREU90250	POREPU90250	POREPUFS90250	9x25cm	40	8

Annex 1
Table of sizes and codes

PORE100250	POREU100250	POREPU100250	POREPUFS100250	10x25cm	40	8
PORE82300	POREU82300	POREPU82300	POREPUFS82300	8.25x30cm	40	8
PORE90300	POREU90300	POREPU90300	POREPUFS90300	9x30cm	40	8
PORE100300	POREU100300	POREPU100300	POREPUFS100300	10x30cm	40	8
PORE90350	POREU90350	POREPU90350	POREPUFS90350	9x35cm	40	8
PORE82350	POREU82350	POREPU82350	POREPUFS82350	8.25x35cm	40	8
PORE100350	POREU100350	POREPU100350	POREPUFS100350	10x35cm	40	8
PORE83415	POREU83415	POREPU83415	POREPUFS83415	8.3x41.5cm	40	8
PORE100160	POREU100160	POREPU100160	POREPUFS100160	10x16cm	60	8
PORE100210	POREU100210	POREPU100210	POREPUFS100210	10x21cm	40	8
PORE100260	POREU100260	POREPU100260	POREPUFS100260	10x26cm	40	8
PORE100400	POREU100400	POREPU100400	POREPUFS100400	10x40cm	40	8
PORE120160	POREU120160	POREPU120160	POREPUFS120160	12x16cm	60	8
PORE150150	POREU150150	POREPU150150	POREPUFS150150	15x15cm	10	24
PORE150200	POREU150200	POREPU150200	POREPUFS150200	15x20cm	10	24
PORE200200	POREU200200	POREPU200200	POREPUFS200200	20x20cm	10	24
PORE2572	POREU2572	POREPU2572	POREPUFS2572	2.5x7.2cm	400	8
PORE83100	POREU83100	POREPU83100	POREPUFS83100	8.3x10cm	100	8
PORE5072	POREU5072	POREPU5072	.....	5x7.2 cm	50	60
			POREPUFS5072		200	8
PORE5075	POREU5075	POREPU5075	POREPUFS5075	5x7.5cm	200	8
PORE70100	POREU70100	POREPU70100	POREPUFS70100	7x10cm	100	8
PORE6075	POREU6075	POREPU6075	POREPUFS6075	6x7.5cm	200	8
PORE60150	.....	.....	.....	6X15cm	60	8
PORE85155	POREU85155	POREPU85155	POREPUFS85155	8.5x15.5cm	60	8
PORE85150	POREU85150	POREPU85150	POREPUFS85150	8.5x15cm	60	8
PORE82120	.....	POREPU82120	.....	8.2x12cm	60	8
.....	POREU7090	.....	.....	7x9cm	100	8
PORE8595	POREU8595	POREPU8595	POREPUFS8595	8.5x9.5cm	100	8
PORE90100	POREU90100	POREPU90100	POREPUFS90100	9x10cm	100	8

Pharmapore IV	Pharmapore PU IV	Pharmapore PU IV Frame Style	Pharmapore PU IV Frame Style (with Pad)	Size	Pieces/Box	Boxes/Case
IVNW6070	IVPU6070	IVFS6070	IVPFS6070	6X7CM	100	16
IVNW7070	IVPU7070	IVFS7070	IVPFS7070	7X7CM	100	16
IVNW7080	IVPU7080	IVFS7080	IVPFS7080	7X8CM	100	16
IVNW80100	IVPU80100	IVFS80100	IVPFS80100	8X10CM	100	16
IVNW82100	IVPU82100	IVFS82100	IVPFS82100	8.25X10CM	100	16
IVNW6085	IVPU6085	IVFS6085	IVPFS6085	6X8.5CM	100	16
IVNW7085	IVPU7085	IVFS7085	IVPFS7085	7X8.5CM	100	16
IVNW85100	IVPU85100	IVFS85100	IVPFS85100	8.5X10CM	100	16
IVNW85115	IVPU85115	IVFS85115	IVPFS85115	8.5X11.5CM	100	16
IVNW7090	IVPU7090	IVFS7090	IVPFS7090	7X9CM	100	16

Annex 1
Table of sizes and codes

IVNW90100	IVPU90100	IVFS90100	IVPFS90100	9X10CM	100	16
IVNW100120	.....	.....	.....	10X12CM	100	16
IVNW100140	.....	.....	.....	10X14CM	100	16
IVNW6080	IVPU6080	IVFS6080	IVPFS6080	6X8CM	100	16
IVNW5057	IVPU5057	IVFS5057	IVPFS5057	5X5.7CM	100	16
IVNW100155	.....	.....	.....	10X15.5CM	50	16
IVNW5055	.....	.....	.....	5X5.5CM	100	16
IVNW6570	.....	.....	.....	6.5X7CM	100	16
.....	.....	IVFS6570ADV	.....	6.5x7CM	50	24
.....	.....	IVFS100155ADV	.....	10x11.5CM	50	24
.....	.....	IVFS7085ADV	.....	7x8.5CM	50	24
.....	.....	IVFS85115ADV	.....	8.5x11.5CM	50	24
.....	.....	IVFS100120ADV	.....	10x12CM	50	24
.....	IVPU100120	IVFS100120	IVPFS100120	10X12CM	50	16
.....	IVPU100140	IVFS100140	IVPFS100140	10X14CM	50	16

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IDNO 1002600046359

ANNEX 2
List of applicable standards

Version no:	05	Date:	11.03.2021

Standard	Title
EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes, 2016
BS EN ISO 14971	Medical devices – Application of risk management to medical devices, 2019
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, 2018
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for cytotoxicity: in vitro methods, 2009
ISO 10993-7	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals, 2008/ AC:2009
DIN EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization, 2014
EN ISO 10993-12	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials, 2012
EN ISO 11135-1	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices, 2014 as amended by (Amd 1:2018)
ISO 14161	Sterilization of health care products-Biological indicators- Guidance for the selection, use and interpretation of results, 2009
ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products, 2018
ISO 11737-2	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process, 2019
USP 71	Sterility Testing
ISO 15223-1	Symbols to be used with medical device labels, labelling and information to be supplied, 2016
BS EN 1041	Information supplied by the manufacturer with medical devices, 2008 + A1:2013
ISO 11607	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, 2019 Part 2: Validation requirements for forming, sealing and assembly processes, 2019
Directive 93/42/EEC as amended by directive 2007/47/EC	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 concerning medical devices
MEDDEV 2.4/1	Guidelines for the Classification of Medical Devices, Rev. 9, 06.2010

ANNEX 2
List of applicable standards

MEDDEV 2.7.1	Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies. Rev 4, 06.2016
ISO 14644	Clean room and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015); Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015) Part 3: Test methods (ISO 14644-3:2019) Part 4: Design, construction and start up (ISO 14644-4:2001) Part 5: Operations (ISO 14644-5:2004) Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments) (ISO 14644-7:2004)
IEC 62366-1	Medical devices -- Part 1: Application of usability engineering to medical devices, 2015
ICH Topic Q 1 A (R2)	Stability Testing of new Drug Substances and Products
ISO 2859-1	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection, 1999 + Cor 1:2001
EN 868-5	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous materials and plastic film construction. Requirements and test methods, 2018
ASTM F1929 - 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration, 2015
DIN 13019	Adhesives for first aid – Dimensions, 2016
FINAT 12	Adhesive coat weight, 2005
AFERA 5001	Self-adhesive tapes. Determination of peel adhesion properties, 2013
FINAT 8	Resistance to shear from a standard surface, 2005
FINAT 9	Loop tack measurement, 2005
BS EN 13726-2	Test methods for primary wound dressings - Part 2: Moisture vapor transmission rate of permeable film dressings, 2002

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Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Pansament ocular adeziv steril	Cure Aid Eye Pad		
2		Emplastru pentru fixarea cateterelor steril	Pharmapore IV	6x7cm	
3		Pansament adeziv steril	Pharmapore	10x30cm	
4		Pansament adeziv steril	Pharmapore	10x10cm	
5		Pansament adeziv steril	Pharmapore	5x7cm	
6		Pansament adeziv steril	Pharmapore	8,2x20cm	
7		Pansament adeziv steril	Pharmapore	8,2x35cm