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:
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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	08.09.2022	13

Company Stamp

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

Annex 1
Table of sizes and codes

Version no:	09	Date:	08/09/2022

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
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
IVNW90100	**IVPU90100**	**IVFS90100**	**IVPFS90100**	9X10CM	100	16

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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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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

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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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