

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® Foot Care Plasters, Cold sore patches, Hydrocolloid dressing's with and without glycerol and Acne Patches Product lines:

- Cure-Aid® Foot care plasters sterile & Non-Sterile.
- CurP-Aici® Foot rare plasters with glycerol sterile & Non-Sterile.
- Cure-Aid® Foot cold sore patches sterile & Non-Sterile.
- Cure-Aid® Foot cold sore patches with glycerol sterile & Non-Sterile.
- Cure-Aid® Foot Hydrocolloid Dressings sterile & Non-Sterile.
- Cure-Aid® Foot Hydrocolloid Dressings with glycerol sterile & Non-Sterile.
- Cure-Aid® Acne Patches.

Indications: Product line with and without glycerol are used as mechanical barrier plaster for the following types of wounds. - Blister - Corn - Callus - Bunion - moderate acne vulgaris - Herpes Simplex Virus that erupt around lips, nose or chin - Weeping cuts and grazes, Blisters, and minor burns.

Code: Annex 1: Table of sizes and codes

Size: Annex1: Table of sizes and codes

GMDNs code: 61945

Applicable standards: Annex 2: List of applicable standards

Classification:

The products Cure-Aid® Foot Care Plasters, Cold sore patches, Hydrocolloid dressing's with and without glycerol and Acne Patches Product lines 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 IIA sterile and Non-sterile Medical device.

Conformity assessment procedure: in accordance with Annex II excluding section 4.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. : 27236

Regulatory Affairs Department	Signature	Place	Date	Version
Dina Desouki	<i>Dina Desouki</i>	Alexandria, Egypt	27.12.2021	07

Company Stamp



Change History:

Version Number	Date	Change	Rationale for Change
02	07.11.2018	Updated DoC SOP and its form Updated DoC form version(2) Addition of "Indication", addition of "Version" 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.
03	31.01.2019	Adding CE certification number. Adding Indications.	To link between DoC and its CE Certificate. To be aligned with indications included in Technical file.
04	16.07.2019	updated DoC form version (3) Change EC/Rep and the related information. 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.	Due to Brexit issues, change of Authorized representative. 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.
05	10.03.2020	Adjusting the name of variants Amend annex 1 (the table of sizes) and annex 2.	to by comply with CE the name of the device. Amend a mistake.
06	15.04.2021	Updating Annex 1 & Annex 2	New coding system To be in compliance with the

			most updated legislative standards.
07	28.12.2021	Amending GMDNS code and packaging configurations	File maintenance

Annex 1

Table of sizes and codes

Version no:	03	Date:	28.12.2021
--------------------	----	--------------	------------

Cure-Aid® Foot Care Plasters/ Cure-Aid Hydrocolloid Dressing	Cure-Aid® Foot Care Plasters/ Cure-Aid Hydrocolloid Dressing Non-Sterile	Cure-Aid® Foot Care Plasters/ Cure-Aid Hydrocolloid Dressing with glycerol	Hydrocolloid PE Foam backing material with glycerol	Size	Pieces/Box	Boxes /Case
COLL938	COLLN938	COLLG938	COLLPEFG938	9 X 38 mm	5	24
COLL1045	COLLN1045	COLLG1045	COLLPEFG1045	10 X 45 mm	5	24
COLL1657	COLLN1657	COLLG1657	COLLPEFG1657	16 X 57 mm	5	24
COLL1938	COLLN1938	COLLG1938	COLLPEFG1938	19 X 38 mm	5	24
COLL1963	COLLN1963	COLLG1963	COLLPEFG1963	19 X 63 mm	5	24
COLL1964	COLLN1964	COLLG1964	COLLPEFG1964	19 X 64 mm	5	24
COLL1972	COLLN1972	COLLG1972	COLLPEFG1972	19 X 72 mm	5	24
COLL1976	COLLN1976	COLLG1976	COLLPEFG1976	19 X 76 mm	5	24
COLL2075	COLLN2075	COLLG2075	COLLPEFG2075	20 X 75 mm	5	24
COLL2572	COLLN2572	COLLG2572	COLLPEFG2572	25 X 72 mm	5	24
COLL2576	COLLN2576	COLLG2576	COLLPEFG2576	25 X 76 mm	5	24
COLL2525	COLLN2525	COLLG2525	COLLPEFG2525	25 X 25 mm	5	24
COLL25	COLLN25	COLLG25	COLLPEFG25	25∅ mm	5	24
COLL2958	COLLN2958	COLLG2958	COLLPEFG2958	29 X 58 mm	5	24
COLL3055	COLLN3055	COLLG3055	COLLPEFG3055	30 X 55 mm	5	24
COLL3064	COLLN3064	COLLG3064	COLLPEFG3064	30 X 64 mm	5	24
COLL3838	COLLN3838	COLLG3838	COLLPEFG3838	38 X 38 mm	5	24
COLL3872	COLLN3872	COLLG3872	COLLPEFG3872	38 X 72 mm	5	24
COLL5072	COLLN5072	COLLG5072	COLLPEFG5072	50 X 72 mm	5	24
COLL50100	COLLN50100	COLLG50100	COLLPEFG50100	50 X 100 mm	10	48
COLL67110	COLLN67110	COLLG67110	COLLPEFG67110	67 x 110 mm OVAL XL	10	48
COLL4863	COLLN4863	COLLG4863	COLLPEFG4863	48 x 63 mm	5	24
COLL3865	COLLN3865	COLLG3865	COLLPEFG3865	38 x 65 mm	5	24
COLL2852	COLLN2852	COLLG2852	COLLPEFG2852	28 x 52 mm	5	24
COLL2868	COLLN2868	COLLG2868	COLLPEFG2868	28 x 68 mm	5	24
COLL2045	COLLN2045	COLLG2045	COLLPEFG2045	20 x 45 mm	5	24
COLL4045	COLLN4045	COLLG4045	COLLPEFG4045	40 x 45 mm	5	24
COLL4060	COLLN4060	COLLG4060	COLLPEFG4060	40 x 60 mm	5	24
COLL4565	COLLN4565	COLLG4565	COLLPEFG4565	45 x 65 mm	5	24
COLL5050	COLLN5050	COLLG5050	COLLPEFG5050	50 x 50 mm	5	24
COLL2065	COLLN2065	COLLG2065	COLLPEFG2065	20 x 65 mm	5	24
COLL4368	COLLN4368	COLLG4368	COLLPEFG4368	43 x 68 mm	5	24

Annex 1

Table of sizes and codes

COLL2060	COLLN2060	COLLG2060	COLLPEFG2060	20 x 60 mm	5	24
COLL2345	COLLN2345	COLLG2345	COLLPEFG2345	23 x 45 mm	5	24
COLL4545	COLLN4545	COLLG4545	COLLPEFG4545	Callus (45 x 45 mm)	6	24
COLL3040	COLLN3040	COLLG3040	COLLPEFG3040	30 x 40 mm	5	24
COLL4343	COLLN4343	COLLG4343	COLLPEFG4343	43 x 43 mm	5	24
COLL4570	COLLN4570			45 x 70 mm	5	24
COLL1848	COLLN1848			18 x 48 mm (corn)	8	24
COLL3855	COLLN3855			38 x 55 mm	5	24
COLL4068	COLLN4068			Heel(40 x 68 mm)	5	24
COLL4070	COLLN4070			Heel(40 x 70 mm)	5	24
COLL5070	COLLN5070			Bunion (50 x 70mm)	5	24

Hydrocolloid Comfort	Hydrocolloid Comfort Non-Sterile	Hydrocolloid Comfort with Glycerol	Hydrocolloid Comfort PE Foam backing material with glycerol	Size	Pieces/Box	Boxes/Case
COLLC1657	COLLCN1657	COLLGC1657	COLLPEFGC1657	16 X 57 mm	5	24
COLLC1938	COLLCN1938	COLLGC1938	COLLPEFGC1938	19 X 38 mm	5	24
COLLC1963	COLLCN1963	COLLGC1963	COLLPEFGC1963	19 X 63 mm	5	24
COLLC1964	COLLCN1964	COLLGC1964	COLLPEFGC1964	19 X 64 mm	5	24
COLLC1972	COLLCN1972	COLLGC1972	COLLPEFGC1972	19 X 72 mm	5	24
COLLC1976	COLLCN1976	COLLGC1976	COLLPEFGC1976	19 X 76 mm	5	24
COLLC2075	COLLCN2075	COLLGC2075	COLLPEFGC2075	20 X 75 mm	5	24
COLLC2572	COLLCN2572	COLLGC2572	COLLPEFGC2572	25 X 72 mm	5	24
COLLC2576	COLLCN2576	COLLGC2576	COLLPEFGC2576	25 X 76 mm	5	24
COLLC2525	COLLCN2525	COLLGC2525	COLLPEFGC2525	25 X 25 mm	5	24
COLLC25	COLLCN25	COLLGC25	COLLPEFGC25	25 ϕ	5	24
COLLC2958	COLLCN2958	COLLGC2958	COLLPEFGC2958	29 X 58 mm	5	24
COLLC3055	COLLCN3055	COLLGC3055	COLLPEFGC3055	30 X 55 mm	5	24
COLLC3064	COLLCN3064	COLLGC3064	COLLPEFGC3064	30 X 64 mm	5	24
COLLC3838	COLLCN3838	COLLGC3838	COLLPEFGC3838	38 X 38 mm	5	24
COLLC3872	COLLCN3872	COLLGC3872	COLLPEFGC3872	38 X 72 mm	5	24
COLLC5072	COLLCN5072	COLLGC5072	COLLPEFGC5072	50 X 72 mm	5	24
COLLC50100	COLLCN50100	COLLGC50100	COLLPEFGC50100	50 X 100 mm	10	48
COLLC67110	COLLCN67110	COLLGC67110	COLLPEFGC67110	67 x 110 mm OVAL XL	10	48
COLLC4863	COLLCN4863	COLLGC4863	COLLPEFGC4863	48 x 63 mm	5	24
COLLC3865	COLLCN3865	COLLGC3865	COLLPEFGC3865	38 x 65 mm	5	24

Annex 1

Table of sizes and codes

COLLC2852	COLLCN2852	COLLGC2852	COLLPEFGC2852	28 x 52 mm	5	24
COLLC2868	COLLCN2868	COLLGC2868	COLLPEFGC2868	28 x 68 mm	5	24
COLLC2045	COLLCN2045	COLLGC2045	COLLPEFGC2045	20 x 45 mm	5	24
COLLC4045	COLLCN4045	COLLGC4045	COLLPEFGC4045	40 x 45 mm	5	24
COLLC4060	COLLCN4060	COLLGC4060	COLLPEFGC4060	40 x 60 mm	5	24
COLLC4565	COLLCN4565	COLLGC4565	COLLPEFGC4565	45 x 65 mm	5	24
COLLC5050	COLLCN5050	COLLGC5050	COLLPEFGC5050	50 x 50 mm	5	24
COLLC2065	COLLCN2065	COLLGC2065	COLLPEFGC2065	20 x 65 mm	5	24
COLLC1750CORN	COLLCN1750CORN	COLLGC1750CORN	COLLPEFGC1750CORN	17 x 50 mm	5	24
COLLC1972CORN	COLLCN1972CORN	COLLGC1972CORN	COLLPEFGC1972CORN	19 x 72 mm	5	24
COLLC1963CORN	COLLCN1963CORN	COLLGC1963CORN	COLLPEFGC1963CORN	19 x 63 mm	5	24
.....	COLLCN7575	COLLGC7575	COLLPEFGC7575	75 x 75 mm	5	24
COLLC60100	COLLCN60100	COLLGC60100	COLLPEFGC60100	60 x 100 mm	10	48
COLLC75100	COLLCN75100	COLLGC75100	COLLPEFGC75100	75 x 100 mm	10	48
COLLC100100	COLLCN100100	COLLGC100100	COLLPEFGC100100	100 x 100 mm	10	48
COLLC3560	COLLCN3560	COLLGC3560	COLLPEFGC3560	35 x 60 mm	5	24
COLLC2055	COLLCN2055	COLLGC2055	COLLPEFGC2055	20 x 55 mm	5	24
COLLC4070	COLLCN4070	COLLGC4070	COLLPEFGC4070	40 x 70 mm	5	24
COLLC3040	COLLCN3040	COLLGC3040	COLLPEFGC3040	30 x 40 mm	5	24
COLLC4368	COLLCN4368	COLLGC4368	COLLPEFGC4368	43 x 68 mm	5	24
COLLC1955	COLLCN1955	COLLGC1955	COLLPEFGC1955	19 x 55 mm	5	24

Cure-Aid Acne Patches / Cure-Aid® cold sore patches	Cure-Aid Acne Patches / Cure-Aid® cold sore patches with Glycerol	Size	Pieces/ Box	Boxes/ Case
COLLSPOT1	COLLGSPOT1	15	20	48
COLLSPOT2	COLLGSPOT2	15	10	48
COLLSPOT3	COLLGSPOT3	10	20	48
COLLSPOT4	COLLGSPOT4	10	10	48
COLLSPOT16	COLLGSPOT16	15	1	48
COLLSPOT24	COLLGSPOT24	assorted	1	48
COLLSPOT12	COLLGSPOT12	assorted	1	48
COLLSPOT8	COLLGSPOT8	assorted	1	48
COLLSPOT5	COLLGSPOT5	12	20	48
COLLSPOT6	COLLGSPOT6	12	10	48

PHARMA PLAST S.A.E
ALEXANDRIA - EGYPT

ANNEX 2

List of applicable standards

Version no:	04	Date:	02/02/2021
--------------------	----	--------------	------------

Standard/ Date	Title
EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes.
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 2.12/1 Rev.8, 2013	Medical Devices Vigilance System
MEDDEV 2.12/1 Rev.8, 2019	Additional Guidance Regarding Vigilance System
MEDDEV 2.12/2 Rev.2, 2012	Clinical evaluation – Post Market Clinical Follow UP
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.
BS EN ISO 14971: 2012	Medical devices – Application of risk management to medical devices.
ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for cytotoxicity: in vitro methods.
ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
EN ISO 11737-1: 2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
ISO 11137-Amd.2:2018	Sterilization of health care products – Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products – Radiation - Part 2: Establishing the sterilization dose
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.
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 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.
ICH Topic Q 1 A (R2)	Stability Testing of new Drug Substances and Products.
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.
FINAT 9	Loop Tack
AFERA 5001 FINAT 1	Peel Adhesion of Colloid
BS EN 13726-2: 2002	Test methods for primary wound dressings Water Vapour Transmition Rate, and Water Vapour Transmition Rate in contact with wound fluids.
US PATENT 4952618	Colloid integrity
FINAT 8	Shear Test
Pharmaplast	Measurement of thickness.
ASTM F 1929-15	Sealing integrity.
USP 71	Sterility testing.
DIN 1309	Measuring dimensions.
patent CA 2382564 c	Cold flow
EN BS 13726-1:2002	Static absorption
EN 13726-1:2002	Fluid handling capacity
EN 868-5 :2018	Seal strength

PHARMA PLAST S.A.E
ALEXANDRIA - EGYPT