

**DECLARATION OF CONFORMITY**

We

**MANUFACTURER'S NAME:**

Pharmaplast SAE

**MANUFACTURER'S ADDRESS:**Amria free zone 23512,  
Alexandria, Egypt**MANUFACTURER'S SRN:**

EG-MF-000004501

**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 regulation (EU) 2017/745, and are manufactured and placed in the market under the sole responsibility of the manufacturer following the regulations of this directive.

**Product information:****Name:** Referred to in Annex I.**Intended Purpose:** Intended to be protective medical supply that protects wounds, cuts, burns, tattoos, and open sores. The sealing bandage keeps out dirt, germs, and water while allowing you would to breathe and have optimal healing conditions.**Code:** Annex 1: Table of sizes and codes**Size:** Annex1: Table of sizes and codes**CND Code:** M030102**Basic UDI-DI Code:** 62220238CureAidNSQ7**Applicable standards:** Annex 2: List of applicable standards**Classification:**

The products Referred to in Annex I are classified as a Short term (continuous use for not more than 30 days) non-invasive devices according to Annex VIII rule 4, and conformity assessment procedure in accordance with Annex III & II of Regulation (EU) 2017/745 of medical device as class I non-sterile.

**Notified body information:****Name:** NA**Address:** NA**Identification Number:** NA**Certificate no. :** NA

Regulatory Affairs Department	Signature	Place	Date	Version
Ereny Nashaat	<i>Ereny Nashaat</i>	Alexandria, Egypt	20-Aug-23	03

Company Stamp



**Change History:**

<b>Version Number</b>	<b>Date</b>	<b>Change</b>	<b>Rationale for Change</b>
01	28-Jun-21	New Issue	Updated based on MDR requirements
02	01-Mar-22	Update annex 1	Adding code 7201
03	20-Aug-23	Update annex 1	Adding code 0601

## Annex 1

### Table of sizes and codes

<b>Version no:</b>	03	<b>Date:</b>	20.08.2023
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Brand Name	Size	Bevaplast code	UDI-DI
Bevaplast Wound Plasters PE Kids Assortment	9x38mm 19x63mm 19x72mm 25mm	0332	8712175913703
Bevaplast Wound Plaster Detectable PE	500x6cm	0340	8712175934937
Bevaplast Wound Plaster Elastic	500x6cm	0341	8712175934944
Bevaplast Wound Plaster Elastic	500x8cm	0342	8712175934951
Bevaplast Wound Plaster Textile	500x6cm	0343	8712175934982
Sana First Aid Wound Plaster PE Kids Assortment	25mm 19x63mm 19x63mm 19x38mm	0361	8712175931653
Sana First Aid Wound Plaster PE	19x72mm	0380	8712175931639
Bevaplast Wound Plaster Detectable PE Assortment	19x72mm 25x72mm 45x64mm 39x72mm 180x20mm 10x6cm	0399	8712175931158
Bevaplast Wound Plaster Elastic Assortment	25x72mm 45x64mm 120x20mm 10x6cm 39x72mm 19x72mm	0400	8712175931141

## Annex 1

### Table of sizes and codes

Bevoplast Wound Plaster PE Kids Assortment	19x72mm 9x38mm 19x63mm 25mm 10x6cm	0402	8712175931004
Bevoplast Wound Plaster PE Assortment	19x72mm 25x72mm 9x38mm 25mm 38x72mm	0405	8712175911815
Sana First Aid Wound Plaster Non-Woven	10x6cm	0591	8712175931608
Sana First Aid Wound Plaster PE	10x6cm	0598	8712175931622
Bevoplast Wound Plaster PE	10x6cm	0603	8712175913642
Sana First Aid Wound Plaster Textile	10x6cm	0607	8712175931592
Bevoplast Wound Plaster Textile	10x6cm	0612	8712175923726
Bevoplast Wound Plaster Detectable Elastic	180x20mm	0634	8712175932490
Bevoplast Wound Plaster Detectable PE	120x20mm	0635	8712175912164
Bevoplast Wound Plaster Detectable PE	180x20mm	0636	8712175912171

**Annex 1**  
**Table of sizes and codes**

Bevaplast Wound Plaster Detectable PE	19x72mm	0637	8712175912102
Bevaplast Wound Plaster Detectable PE	25x72mm	0638	8712175912119
Bevaplast Wound Plaster Elastic	68x38mm	0643	8712175912300
Bevaplast Wound Plaster Elastic	120x20mm	0644	8712175912324
Bevaplast Wound Plaster Elastic	180x20mm	0645	8712175912331
Bevaplast Wound Plaster Kids PE	10x6cm	0761	8712175913710
Sana First Aid Wound Plaster PU Assortment	19x38mm 19x72mm 25x72mm 30x55mm	6206	8712175931660
Bevaplast Wound Plaster Non-Woven Silicone	19x72mm	7028	8712175934968
Family Pack	100 x 60 mm 9 x 38 mm 25 mm 19 x 63 mm 19 x 72 mm	7201	8712175935292
Bevaplast Wound Plaster PE	10x6cm	0601	8712175931837

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## ANNEX 2

### List of applicable standards

<b>Version no:</b>	01	<b>Date:</b>	28/06/2021
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Standard	Title
EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes.
EN ISO 14971: 2019	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.
MDR “2017/745”	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
EN ISO 11737-1: 2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
ISO 11737-2: 2019	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
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.
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) 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.
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.
ASTM F88 :2015	Standard Test Method for Seal Strength of Flexible Barrier Materials.

## ANNEX 2

### List of applicable standards

ASTM F1929:2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
AFERA 5001 FINAT 1	Peel adhesion of non-woven border (N/25 mm)
PHARMAPLAST	Piece dimension Wound Pad dimension Pouch dimension

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