

DEKLARACJA ZGODNOŚCI

My

NAZWA PRODUCENTA:

Pharmaplast SAE ADRES

PRODUCENTA:Amria free zone 23512,
Aleksandria, Egipt**SRN PRODUCENTA:**

EG-MF-000004501

NAZWA UPOWAŻNIONEGO PRZEDSTAWICIELA:

EC Rep Ltd,

ADRES UPOWAŻNIONEGO PRZEDSTAWICIELA:5 Fitzwilliam Square East, Dublin 2, D02 R744,
Irlandia. Tel: +353 1 2 544 944

E-mail: info@ecrep.ie

Oświadczam, że produkt objęty niniejszą deklaracją jest zgodny z wymogami załącznika I do rozporządzenia (UE) 2017/745 oraz jest produkowany i wprowadzany do obrotu na wyłączną odpowiedzialność producenta zgodnie z przepisami tej dyrektywy.

Informacje o produkcie:

Nazwa: Medyczne taśmy samoprzylepne „Pharmafix, Pharmafix PU, Airoplast, Neoplast, Pharmamed, Waterproof Neoplast, Waterproof Pharmamed, Waterproof Pharmafix i Silkplast”. Przeznaczenie: Medyczne taśmy samoprzylepne są hipoalergiczne do zabezpieczania cewników i rurek drenażowych oraz zmniejszania ryzyka obrażeń.

Kod: Załącznik 1: Tabela rozmiarów i kodów**Rozmiar: Załącznik 1: Tabela rozmiarów i kodów****Kod CND: M050101****Podstawowy kod UDI-DI: 62220238TapesVL****Obowiązujące normy: Załącznik 2: Lista obowiązujących norm****Klasyfikacja:**

Produkty Medyczne taśmy samoprzylepne „Pharmafix, Pharmafix PU, Airoplast, Neoplast, Pharmamed, Waterproof Neoplast, Waterproof Pharmamed, Waterproof Pharmafix i Silkplast” są klasyfikowane jako urządzenia nieinwazyjne krótkoterminowe (ciągłe użytkowanie nie dłużej niż 30 dni) wg Aneks VIII zasada 1 oraz procedura oceny zgodności zgodnie z Aneksem III i II Rozporządzenia (UE) 2017/745 dla wyrobu medycznego jako niesterylnej klasy I.

Informacje o jednostce notyfikowanej:

Nazwa: NA

Adres: NA

Numer identyfikacyjny: NA

Nr certyfikatu: NA

Departament Regulacji	Podpis	Miejsce	Data	Wersja
Ereny Nashaat	Podpis nieczytelny	Alexandria, Egipt	8 czerwca 2021	01

Pieczęć firmowaPieczęć firmy
PHARMAPLAST

Historia zmian

Wersja nr	Data	Zmiana	Uzasadnienie zmian
01	8 czerwca 2021	Nowe wydanie	Zaktualizowano na podstawie wymagań MDR

Aneks 1

Tabela rozmiarów i kodów

Wersja nr	01	Data:	08.06.2021
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Nazwa handlowa	Numer referencyjny	Rozmiar (cm)	UDI-DI
Airopplast®	Airopplast® Perforated		
	AIRO124550	1.25cmx4.55m	6223003733704
	AIRO254550	2.5cmx4.55m	6223003734398
	AIRO504550	5cmx4.55m	6223003734404
	AIRO754550	7.5cmx4.55m	6223003734411
	AIRO1004550	10cmx4.55m	6223003734428
	AIRO125000	1.25cmx5m	6223003731854
	AIRO255000	2.5cmx5m	6224000132255
	AIRO505000	5cmx5m	6224000132521
	AIRO755000	7.5cmx5m	6224000549916
	AIRO1005000	10cmx5m	6224000132224
	AIRO129140	1.25cmx9.14m	6223003733650
	AIRO259140	2.5cmx9.14m	6223003733667
	AIRO509140	5cmx9.14m	6223003733674
	AIRO759140	7.5cmx9.14m	6223003733681
	AIRO1009140	10cmx9.14m	6223003733698
	AIRO1210000	1.25cmx10m	6223003737931
	AIRO2510000	2.5cmx10m	6223003736330
	AIRO5010000	5cmx10m	6223003736316
	AIRO7510000	7.5cmx10m	6223003737948
	AIRO10010000	10cmx10m	6223003734350
	AIRO10015000	10cmX15m	6222023895249
	AIROSET	Assorted	6222023804371
	Airopplast® Non-Perforated		
	AIRO124550N	1.25cmx4.55m	6222023849617
	AIRO254550N	2.5cmx4.55m	6223003733711
	AIRO504550N	5cmx4.55m	6223003733728
	AIRO754550N	7.5cmx4.55m	6223003733735
	AIRO1004550N	10cmx4.55m	6223003733742
	AIRO125000N	1.25cmx5m	6223003733605
	AIRO255000N	2.5cmx5m	6224000549909
	AIRO505000N	5cmx5m	6224000132248
	AIRO755000N	7.5cmx5m	6223003733636
	AIRO1005000N	10cmx5m	6223003733643
	AIRO129140N	1.25cmx9.14m	6223003733647
	AIRO259140N	2.5cmx9.14m	6223003733654
	AIRO509140N	5cmx9.14m	6223003733661
	AIRO759140N	7.5cmx9.14m	6223003733678
	AIRO1009140N	10cmx9.14m	6223003733685

Aneks 1

Tabela rozmiarów i kodów

	AIRO1210000N	1.25cmx10m	6222023849624
	AIRO2510000N	2.5cmx10m	6222023849631
	AIRO5010000N	5cmx10m	6222023849648
	AIRO7510000N	7.5cmx10m	6222023849655
	AIRO10010000N	10cmx10m	6222023849662
	AIROSETN	Assorted	6222023849679
Neoplast®	NEO124550	1.25cmx4.55m	6222023849686
	NEO254550	2.5cmx4.55m	6223003733414
	NEO504550	5cmx4.55m	6223003733186
	NEO754550	7.5cmx4.55m	6223003733193
	NEO1004550	10cmx4.55m	6223003733209
	NEO125000	1.25cmx5m	6224000132439
	NEO255000	2.5cmx5m	6224000132446
	NEO505000	5cmx5m	6224000132514
	NEO755000	7.5cmx5m	6224000132057
	NEO1005000	10cmx5m	6224000132040
	NEO129140	1.25cmx9.14m	6223003733759
	NEO259140	2.5cmx9.14m	6223003733766
	NEO509140	5cmx9.14m	6223003733773
	NEO759140	7.5cmx9.14m	6223003733780
	NEO1009140	10cmx9.14m	6223003733797
	NEO1210000	1.25cmx10m	6223003737955
	NEO2510000	2.5cmx10m	6223003737962
	NEO5010000	5cmx10m	6223003737979
	NEO7510000	7.5cmx10m	6223003737986
	NEO10010000	10cmx10m	6223003737993
	NEO1805000	18cmx5m	6222023895263
	NEOSET	Assorted	6223004863721
	NEO1005000P	10cmx5m Perforated	6224000132613
	NEO1805000P	18cmx5m Perforated	6224000132606
	NEO1004000P	10cmx4m Perforated	6222023849198
	NEO1804000P	18cmx4m Perforated	6223003731205
	Waterproof Neoplast®		
	NEOWF124550	1.25cmx4.55m	6222023849693
	NEOWF254550	2.5cmx4.55m	6222023849709
	NEOWF504550	5cmx4.55m	6222023849716
	NEOWF754550	7.5cmx4.55m	6222023849723
	NEOWF1004550	10cmx4.55m	6223003733483
	NEOWF125000	1.25cmx5m	6223003731250
	NEOWF255000	2.5cmx5m	6223003731267
	NEOWF505000	5cmx5m	6223003731274
	NEOWF755000	7.5cmx5m	6223003731281
	NEOWF1005000	10cmx5m	6223003731298
	NEOWF129140	1.25cmx9.14m	6222023849730
	NEOWF259140	2.5cmx9.14m	6222023849747

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Tabela z rozmiarami i kodami

	NEOWF509140	5cmx9.14m	6222023849754
	NEOWF759140	7.5cmx9.14m	6222023849761
	NEOWF1009140	10cmx9.14m	6222023849778
	NEOWF1210000	1.25cmx10m	6222023849785
	NEOWF2510000	2.5cmx10m	6222023849792
	NEOWF5010000	5cmx10m	6222023849808
	NEOWF7510000	7.5cmx10m	6222023849815
	NEOWF10010000	10cmx10m	6222023849822
	NEOWF1805000	18cmx5m	6222023895256
	NEOWFSET	Assorted	6222023849839
	NEOWF1005000P	10cmx5m Perforated	6222023849846
	NEOWF1805000P	18cmx5m Perforated	6222023849853
	NEOWF1004000P	10cmx4m Perforated	6222023849860
	NEOWF1804000P	18cmx4m Perforated	6222023849877
Pharmamed®	MED124550	1.25cmx4.55m	6223003734589
	MED254550	2.5cmx4.55m	6223003731908
	MED504550	5cmx4.55m	6223004861802
	MED754550	7.5cmx4.55m	6223003734619
	MED1004550	10cmx4.55m	6223003734626
	MED125000	1.25cmx5m	6224000132507
	MED255000	2.5cmx5m	6224000132491
	MED505000	5cmx5m	6224000132828
	MED755000	7.5cmx5m	6223003731335
	MED1005000	10cmx5m	6223003731342
	MED129140	1.25cmx9.14m	6223003733131
	MED259140	2.5cmx9.14m	6223003730567
	MED509140	5cmx9.14m	6223003730574
	MED759140	7.5cmx9.14m	6223003733162
	MED1009140	10cmx9.14m	6223003733995
	MED1210000	1.25cmx10m	6223003738006
	MED2510000	2.5cmx10m	6223003738013
	MED5010000	5cmx10m	6223003738020
	MED7510000	7.5cmx10m	6223003738037
	MED10010000	10cmx10m	6223003738044
	MEDSET	Assorted	6222023805002
	Pharmamed Waterproof		
	MEDWF124550	1.25x455cm	6222023849884
	MEDWF254550	2.5x455cm	6223003734596
	MEDWF504550	5x455cm	6223003734602
	MEDWF7545	7.5x455cm	6222023849891
	MEDWF1004550	10x455cm	6222023849907
	MEDWF125000	1.25x500cm	6223003731304
	MEDWF255000	2.55x500cm	6223003731311
	MEDWF505000	5x500cm	6223003731328
	MEDWF755000	7.5x500cm	6222023849914

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Tabela rozmiarów i kodów

	MEDWF1005000	10x500cm	6222023849921
	MEDWF129100	1.25x910cm	6222023849938
	MEDWF259100	2.5x910cm	6222023849945
	MEDWF509100	5x910cm	6222023849952
	MEDWF759100	7.5x910cm	6222023849969
	MEDWF1009100	10x910cm	6222023849976
	MEDWF1210000	1.25x1000cm	6222023849983
	MEDWF2510000	2.5x1000cm	6222023849990
	MEDWF5010000	5x1000cm	6222023850002
	MEDWF7510000	7.5x1000cm	6222023850019
	MEDWF10010000	10x1000cm	6222023850026
Silkplast®	SILK124550	1.25cmx4.55m	6223003734633
	SILK254550	2.5cmx4.55m	6223003734657
	SILK504550	5cmx4.55m	6223003734664
	SILK754550	7.5cmx4.55m	6223003734671
	SILK1004550	10cmx4.55m	6223003734152
	SILK125000	1.25cmx5m	6224000132415
	SILK255000	2.5cmx5m	6223003733513
	SILK505000	5cmx5m	6223003733520
	SILK755000	7.5cmx5m	6223003733537
	SILK1005000	10cmx5m	6223003733544
	SILK129140	1.25cmx9.14m	6223003733551
	SILK259140	2.5cmx9.14m	6223003733100
	SILK509140	5cmx9.14m	6223003733117
	SILK759140	7.5cmx9.14m	6223003733124
	SILK1009140	10cmx9.14m	6223003733599
	SILK1210000	1.25cmx10m	6223003738051
	SILK2510000	2.5cmx10m	6223003738068
	SILK5010000	5cmx10m	6223003738075
	SILK7510000	7.5cmx10m	6223003738082
	SILK10010000	10cmx10m	6223003738099
	SILK1805000	18cmx5m	6224000549558
	SILKSET	Assorted	6222023849211
	SILK1005000P	10cmx5m Perforated	6223003731373
	SILK1805000P	18cmx5m Perforated	6224000549473
	SILK1004000P	10cmx4m Perforated	6222023849204
	SILK1804000P	18cmx4m Perforated	6224000549480
Pharmafix®	Pharmafix® Waterproof		
	FIXWF124550	1.25cmx4.55m	6222023850194
	FIXWF254550	2.5cmx4.55m	6222023850200
	FIXWF504550	5cmx4.55m	6222023850217
	FIXWF754550	7.5cmx4.55m	6222023850224
	FIXWF1004550	10cmx4.55m	6222023850231
	FIXWF125000	1.25cmx5m	6222023850248
	FIXWF255000	2.5cmx5m	6222023850255

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Tabela rozmiarów i kodów

	FIXWF505000	5cmx5m	6222023850262
	FIXWF755000	7.5cmx5m	6222023850279
	FIXWF1005000	10cmx5m	6222023850286
	FIXWF129140	1.25cmx9.14m	6222023850293
	FIXWF259140	2.5cmx9.14m	6223003736491
	FIXWF509140	5cmx9.14m	6223003736507
	FIXWF759140	7.5cmx9.14m	6223003736514
	FIXWF1009140	10cmx9.14m	6223003736521
	FIXWF1210000	1.25cmx10m	6222023850309
	FIXWF2510000	2.5cmx10m	6222023850316
	FIXWF5010000	5cmx10m	6222023850323
	FIXWF7510000	7.5cmx10m	6222023850330
	FIXWF10010000	10cmx10m	6222023850347
	Pharmafix®		
	FIX254550	2.5cmx4.55m	6222023850033
	FIX504550	5cmx4.55m	6222023850040
	FIX754550	7.5cmx4.55m	6222023850057
	FIX1004550	10cmx4.55m	6222023850064
	FIX1504550	15cmx4.55m	6222023850071
	FIX2004550	20cmx4.55m	6222023850088
	FIX3004550	30cmx4.55m	6222023850095
	FIX255000	2.5cmx5m	6223004864841
	FIX505000	5cmx5m	6224000549947
	FIX755000	7.5cmx5m	6223004864858
	FIX1005000	10cmx5m	6223003731380
	FIX1505000	15cmx5m	6223003738983
	FIX2005000	20cmx5m	6223004865930
	FIX3005000	30cmx5m	6222023850101
	FIX259140	2.5cmx9.14m	6222023850118
	FIX509140	5cmx9.14m	6222023850125
	FIX759140	7.5cmx9.14m	6222023850132
	FIX1009140	10cmx9.14m	6222023850149
	FIX1509140	15cmx9.14m	6222023850156
	FIX2009140	20cmx9.14m	6222023850163
	FIX3009140	30cmx9.14m	6222023850170
	FIX2510000	2.5cmx10m	6224000549848
	FIX5010000	5cmx10m	6224000549855
	FIX7510000	7.5cmx10m	6223004868313
	FIX10010000	10cmx10m	6224000549862
	FIX15010000	15cmx10m	6224007257067
	FIX20010000	20cmx10m	6224000549879
	FIX30010000	30cmx10m	6224000549886
	FIXSET	Assorted	6222023850187
	Pharmafix® PU		
	FIXPU254550	2.5cmx4.55m	6222023849228

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Tabela rozmiarów i kodów

FIXPU504550	5cmx4.55m	6222023849235
FIXPU754550	7.5cmx4.55m	6222023849242
FIXPU1004550	10cmx4.55m	6222023849259
FIXPU1504550	15cmx4.55m	6222023849266
FIXPU2004550	20cmx4.55m	6222023849273
FIXPU3004550	30cmx4.55m	6222023849280
FIXPU255000	2.5cmx5m	6222023800434
FIXPU505000	5cmx5m	6223003737160
FIXPU755000	7.5cmx5m	6223003733377
FIXPU1005000	10cmx5m	6223003733384
FIXPU1505000	15cmx5m	6222023849297
FIXPU2005000	20cmx5m	6222023849303
FIXPU3005000	30cmx5m	6222023849310
FIXPU259140	2.5cmx9.14m	6222023849327
FIXPU509140	5cmx9.14m	6222023849334
FIXPU759140	7.5cmx9.14m	6222023849341
FIXPU1009140	10cmx9.14m	6222023849358
FIXPU1509140	15cmx9.14m	6222023849365
FIXPU2009140	20cmx9.14m	6222023849372
FIXPU3009140	30cmx9.14m	6222023849389
FIXPU2510000	2.5cmx10m	6223003730758
FIXPU5010000	5cmx10m	6224007257074
FIXPU7510000	7.5cmx10m	6223003734442
FIXPU10010000	10cmx10m	6224007257081
FIXPU15010000	15cmx10m	6223003730246
FIXPU20010000	20cmx10m	6223003732578
FIXPU30010000	30cmx10m	6223003730895
FIXPUSET	Assorted	6222023849396

PHARMA PLAST S.A.E
ALEXANDRIA - EGYPT

ZAŁĄCZNIK 2

Lista obowiązujących norm

Wersja nr:	01	Data:	08/06/2021
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Standard : Data	Tytuł
EN ISO 13485: 2016	Wyroby medyczne — Systemy zarządzania jakością — Wymagania do celów prawnych.
ISO 14971: 2012	Wyroby medyczne – Zastosowanie zarządzania ryzykiem do wyrobów medycznych.
EN ISO 10993-1: 2018	Biologiczna ocena wyrobów medycznych - Część 1: Ocena i testowanie w ramach procesu zarządzania ryzykiem.
EN ISO 10993-5: 2009	Biologiczna ocena wyrobów medycznych – Część 5: Badania cytotoksyczności: metody in vitro.
DIN EN ISO 10993-10:2014	Biologiczna ocena wyrobów medycznych – Część 10: Testy na podrażnienie i uczulenie skóry.
EN ISO 10993-12: 2012	Biologiczna ocena wyrobów medycznych – Część 12: Przygotowanie próbki i materiały odniesienia.
ISO 15223-1: 2016	Symbole do stosowania z etykietami wyrobów medycznych, etykietami i informacjami, które należy dostarczyć.
BS EN 1041: 2008 + A1:2013	Informacje dostarczone przez producenta wraz z wyrobami medycznymi.
MDR “2017/745”	Rozporządzenie Parlamentu Europejskiego i Rady (UE) 2017/745 z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych, zmieniające dyrektywę 2001/83/WE, rozporządzenie (WE) nr 178/2002 i rozporządzenie (WE) nr 1223/2009 oraz uchylające Dyrektywę Rady 90/385/EWG i 93/42/EWG
IEC 62366-1: 2015	Wyroby medyczne -- Część 1: Zastosowanie inżynierii użyteczności do wyrobów medycznych.
ISO 2859-1: 1999	Procedury pobierania próbek do kontroli według atrybutów -- Część 1: Schematy pobierania próbek indeksowane według dopuszczalnej granicy jakości (AQL) dla kontroli partii po partii.
BS EN 13726-2: 2002	Metody badań podstawowych opatrunków na rany - Część 2: Szybkość przepuszczania pary wodnej opatrunków z folii przepuszczalnej.
FINAT 12	Określenie pomiaru wagi
AFERA 5001	Pomiar przyczepności odrywania ze stali nierdzewnej
ASTM D 1938	Wytrzymałość na rozdarcie surowców
ASTM D 1777-96: 2007	Standardowa metoda badania grubości materiałów tekstylnych
AFERA 4013	Rozwinięcie przyczepność taśm samoprzylepnych
ASTM D 903-98: 2017	Wyznaczanie obciążenia zdzierania

PHARMA PLAST S.A.E
ALEXANDRIA - EGYPT

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:

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 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: Medical adhesive tapes "Pharmafix, Pharmafix PU, Airopplast, Neoplast, Pharmamed, Waterproof Neoplast, Waterproof Pharmamed, Waterproof Pharmafix and Silkplast".

Intended Purpose: Medical adhesive tapes are used to be Hypoallergenic for securing catheters and drainage tubes and reduce the risk of injury.

Code: Annex 1: Table of sizes and codes

Size: Annex1: Table of sizes and codes

CND Code: M050101

Basic UDI-DI Code: 62220238TapesVL

Applicable standards: Annex 2: List of applicable standards

Classification:

The products Medical adhesive tapes "Pharmafix, Pharmafix PU, Airopplast, Neoplast, Pharmamed, Waterproof Neoplast, Waterproof Pharmamed, Waterproof Pharmafix and Silkplast" are classified as a Short term (continuous use for not more than 30 days) non-invasive devices according to Annex VIII rule 1, 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	08-Jun-21	01

Company Stamp



Change History:

Version Number	Date	Change	Rationale for Change
01	08-Jun-21	New Issue	Updated based on MDR requirements

Annex 1

Table of sizes and codes

Version no:	01	Date:	08.06.2021
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Brand Name	Reference Number	Size (cm)	UDI-DI
Airoplast®	Airoplast® Perforated		
	AIRO124550	1.25cmx4.55m	6223003733704
	AIRO254550	2.5cmx4.55m	6223003734398
	AIRO504550	5cmx4.55m	6223003734404
	AIRO754550	7.5cmx4.55m	6223003734411
	AIRO1004550	10cmx4.55m	6223003734428
	AIRO125000	1.25cmx5m	6223003731854
	AIRO255000	2.5cmx5m	6224000132255
	AIRO505000	5cmx5m	6224000132521
	AIRO755000	7.5cmx5m	6224000549916
	AIRO1005000	10cmx5m	6224000132224
	AIRO129140	1.25cmx9.14m	6223003733650
	AIRO259140	2.5cmx9.14m	6223003733667
	AIRO509140	5cmx9.14m	6223003733674
	AIRO759140	7.5cmx9.14m	6223003733681
	AIRO1009140	10cmx9.14m	6223003733698
	AIRO1210000	1.25cmx10m	6223003737931
	AIRO2510000	2.5cmx10m	6223003736330
	AIRO5010000	5cmx10m	6223003736316
	AIRO7510000	7.5cmx10m	6223003737948
	AIRO10010000	10cmx10m	6223003734350
	AIRO10015000	10cmX15m	6222023895249
	AIROSET	Assorted	6222023804371
	Airoplast® Non-Perforated		
	AIRO124550N	1.25cmx4.55m	6222023849617
	AIRO254550N	2.5cmx4.55m	6223003733711
	AIRO504550N	5cmx4.55m	6223003733728
	AIRO754550N	7.5cmx4.55m	6223003733735
	AIRO1004550N	10cmx4.55m	6223003733742
	AIRO125000N	1.25cmx5m	6223003733605
	AIRO255000N	2.5cmx5m	6224000549909
	AIRO505000N	5cmx5m	6224000132248
	AIRO755000N	7.5cmx5m	6223003733636
	AIRO1005000N	10cmx5m	6223003733643
	AIRO129140N	1.25cmx9.14m	6223003733647
	AIRO259140N	2.5cmx9.14m	6223003733654
	AIRO509140N	5cmx9.14m	6223003733661
	AIRO759140N	7.5cmx9.14m	6223003733678
	AIRO1009140N	10cmx9.14m	6223003733685

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Neoplast®	AIRO1210000N	1.25cmx10m	6222023849624
	AIRO2510000N	2.5cmx10m	6222023849631
	AIRO5010000N	5cmx10m	6222023849648
	AIRO7510000N	7.5cmx10m	6222023849655
	AIRO10010000N	10cmx10m	6222023849662
	AIROSETN	Assorted	6222023849679
	NEO124550	1.25cmx4.55m	6222023849686
	NEO254550	2.5cmx4.55m	6223003733414
	NEO504550	5cmx4.55m	6223003733186
	NEO754550	7.5cmx4.55m	6223003733193
	NEO1004550	10cmx4.55m	6223003733209
	NEO125000	1.25cmx5m	6224000132439
	NEO255000	2.5cmx5m	6224000132446
	NEO505000	5cmx5m	6224000132514
	NEO755000	7.5cmx5m	6224000132057
	NEO1005000	10cmx5m	6224000132040
	NEO129140	1.25cmx9.14m	6223003733759
	NEO259140	2.5cmx9.14m	6223003733766
	NEO509140	5cmx9.14m	6223003733773
	NEO759140	7.5cmx9.14m	6223003733780
	NEO1009140	10cmx9.14m	6223003733797
	NEO1210000	1.25cmx10m	6223003737955
	NEO2510000	2.5cmx10m	6223003737962
	NEO5010000	5cmx10m	6223003737979
	NEO7510000	7.5cmx10m	6223003737986
	NEO10010000	10cmx10m	6223003737993
	NEO1805000	18cmx5m	6222023895263
	NEOSET	Assorted	6223004863721
	NEO1005000P	10cmx5m Perforated	6224000132613
	NEO1805000P	18cmx5m Perforated	6224000132606
	NEO1004000P	10cmx4m Perforated	6222023849198
	NEO1804000P	18cmx4m Perforated	6223003731205
	Waterproof Neoplast®		
	NEOWF124550	1.25cmx4.55m	6222023849693
	NEOWF254550	2.5cmx4.55m	6222023849709
	NEOWF504550	5cmx4.55m	6222023849716
	NEOWF754550	7.5cmx4.55m	6222023849723
	NEOWF1004550	10cmx4.55m	6223003733483
	NEOWF125000	1.25cmx5m	6223003731250
	NEOWF255000	2.5cmx5m	6223003731267
	NEOWF505000	5cmx5m	6223003731274
	NEOWF755000	7.5cmx5m	6223003731281
	NEOWF1005000	10cmx5m	6223003731298
	NEOWF129140	1.25cmx9.14m	6222023849730
	NEOWF259140	2.5cmx9.14m	6222023849747

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	NEOWF509140	5cmx9.14m	6222023849754
	NEOWF759140	7.5cmx9.14m	6222023849761
	NEOWF1009140	10cmx9.14m	6222023849778
	NEOWF1210000	1.25cmx10m	6222023849785
	NEOWF2510000	2.5cmx10m	6222023849792
	NEOWF5010000	5cmx10m	6222023849808
	NEOWF7510000	7.5cmx10m	6222023849815
	NEOWF10010000	10cmx10m	6222023849822
	NEOWF1805000	18cmx5m	6222023895256
	NEOWFSET	Assorted	6222023849839
	NEOWF1005000P	10cmx5m Perforated	6222023849846
	NEOWF1805000P	18cmx5m Perforated	6222023849853
	NEOWF1004000P	10cmx4m Perforated	6222023849860
	NEOWF1804000P	18cmx4m Perforated	6222023849877
Pharmamed®	MED124550	1.25cmx4.55m	6223003734589
	MED254550	2.5cmx4.55m	6223003731908
	MED504550	5cmx4.55m	6223004861802
	MED754550	7.5cmx4.55m	6223003734619
	MED1004550	10cmx4.55m	6223003734626
	MED125000	1.25cmx5m	6224000132507
	MED255000	2.5cmx5m	6224000132491
	MED505000	5cmx5m	6224000132828
	MED755000	7.5cmx5m	6223003731335
	MED1005000	10cmx5m	6223003731342
	MED129140	1.25cmx9.14m	6223003733131
	MED259140	2.5cmx9.14m	6223003730567
	MED509140	5cmx9.14m	6223003730574
	MED759140	7.5cmx9.14m	6223003733162
	MED1009140	10cmx9.14m	6223003733995
	MED1210000	1.25cmx10m	6223003738006
	MED2510000	2.5cmx10m	6223003738013
	MED5010000	5cmx10m	6223003738020
	MED7510000	7.5cmx10m	6223003738037
	MED10010000	10cmx10m	6223003738044
	MEDSET	Assorted	6222023805002
	Pharmamed Waterproof		
	MEDWF124550	1.25x455cm	6222023849884
	MEDWF254550	2.5x455cm	6223003734596
	MEDWF504550	5x455cm	6223003734602
	MEDWF7545	7.5x455cm	6222023849891
	MEDWF1004550	10x455cm	6222023849907
	MEDWF125000	1.25x500cm	6223003731304
	MEDWF255000	2.55x500cm	6223003731311
	MEDWF505000	5x500cm	6223003731328
	MEDWF755000	7.5x500cm	6222023849914

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	MEDWF1005000	10x500cm	6222023849921
	MEDWF129100	1.25x910cm	6222023849938
	MEDWF259100	2.5x910cm	6222023849945
	MEDWF509100	5x910cm	6222023849952
	MEDWF759100	7.5x910cm	6222023849969
	MEDWF1009100	10x910cm	6222023849976
	MEDWF1210000	1.25x1000cm	6222023849983
	MEDWF2510000	2.5x1000cm	6222023849990
	MEDWF5010000	5x1000cm	6222023850002
	MEDWF7510000	7.5x1000cm	6222023850019
	MEDWF10010000	10x1000cm	6222023850026
	MEDWF10010000	10x1000cm	6222023850026
Silkplast®	SILK124550	1.25cmx4.55m	6223003734633
	SILK254550	2.5cmx4.55m	6223003734657
	SILK504550	5cmx4.55m	6223003734664
	SILK754550	7.5cmx4.55m	6223003734671
	SILK1004550	10cmx4.55m	6223003734152
	SILK125000	1.25cmx5m	6224000132415
	SILK255000	2.5cmx5m	6223003733513
	SILK505000	5cmx5m	6223003733520
	SILK755000	7.5cmx5m	6223003733537
	SILK1005000	10cmx5m	6223003733544
	SILK129140	1.25cmx9.14m	6223003733551
	SILK259140	2.5cmx9.14m	6223003733100
	SILK509140	5cmx9.14m	6223003733117
	SILK759140	7.5cmx9.14m	6223003733124
	SILK1009140	10cmx9.14m	6223003733599
	SILK1210000	1.25cmx10m	6223003738051
	SILK2510000	2.5cmx10m	6223003738068
	SILK5010000	5cmx10m	6223003738075
	SILK7510000	7.5cmx10m	6223003738082
	SILK10010000	10cmx10m	6223003738099
	SILK1805000	18cmx5m	6224000549558
	SILKSET	Assorted	6222023849211
	SILK1005000P	10cmx5m Perforated	6223003731373
	SILK1805000P	18cmx5m Perforated	6224000549473
	SILK1004000P	10cmx4m Perforated	6222023849204
	SILK1804000P	18cmx4m Perforated	6224000549480
Pharmafix®	Pharmafix® Waterproof		
	FIXWF124550	1.25cmx4.55m	6222023850194
	FIXWF254550	2.5cmx4.55m	6222023850200
	FIXWF504550	5cmx4.55m	6222023850217
	FIXWF754550	7.5cmx4.55m	6222023850224
	FIXWF1004550	10cmx4.55m	6222023850231
	FIXWF125000	1.25cmx5m	6222023850248
	FIXWF255000	2.5cmx5m	6222023850255

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	FIXWF505000	5cmx5m	6222023850262
	FIXWF755000	7.5cmx5m	6222023850279
	FIXWF1005000	10cmx5m	6222023850286
	FIXWF129140	1.25cmx9.14m	6222023850293
	FIXWF259140	2.5cmx9.14m	6223003736491
	FIXWF509140	5cmx9.14m	6223003736507
	FIXWF759140	7.5cmx9.14m	6223003736514
	FIXWF1009140	10cmx9.14m	6223003736521
	FIXWF1210000	1.25cmx10m	6222023850309
	FIXWF2510000	2.5cmx10m	6222023850316
	FIXWF5010000	5cmx10m	6222023850323
	FIXWF7510000	7.5cmx10m	6222023850330
	FIXWF10010000	10cmx10m	6222023850347
	Pharmafix®		
	FIX254550	2.5cmx4.55m	6222023850033
	FIX504550	5cmx4.55m	6222023850040
	FIX754550	7.5cmx4.55m	6222023850057
	FIX1004550	10cmx4.55m	6222023850064
	FIX1504550	15cmx4.55m	6222023850071
	FIX2004550	20cmx4.55m	6222023850088
	FIX3004550	30cmx4.55m	6222023850095
	FIX255000	2.5cmx5m	6223004864841
	FIX505000	5cmx5m	6224000549947
	FIX755000	7.5cmx5m	6223004864858
	FIX1005000	10cmx5m	6223003731380
	FIX1505000	15cmx5m	6223003738983
	FIX2005000	20cmx5m	6223004865930
	FIX3005000	30cmx5m	6222023850101
	FIX259140	2.5cmx9.14m	6222023850118
	FIX509140	5cmx9.14m	6222023850125
	FIX759140	7.5cmx9.14m	6222023850132
	FIX1009140	10cmx9.14m	6222023850149
	FIX1509140	15cmx9.14m	6222023850156
	FIX2009140	20cmx9.14m	6222023850163
	FIX3009140	30cmx9.14m	6222023850170
	FIX2510000	2.5cmx10m	6224000549848
	FIX5010000	5cmx10m	6224000549855
	FIX7510000	7.5cmx10m	6223004868313
	FIX10010000	10cmx10m	6224000549862
	FIX15010000	15cmx10m	6224007257067
	FIX20010000	20cmx10m	6224000549879
	FIX30010000	30cmx10m	6224000549886
	FIXSET	Assorted	6222023850187
	Pharmafix® PU		
	FIXPU254550	2.5cmx4.55m	6222023849228

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FIXPU504550	5cmx4.55m	6222023849235
FIXPU754550	7.5cmx4.55m	6222023849242
FIXPU1004550	10cmx4.55m	6222023849259
FIXPU1504550	15cmx4.55m	6222023849266
FIXPU2004550	20cmx4.55m	6222023849273
FIXPU3004550	30cmx4.55m	6222023849280
FIXPU255000	2.5cmx5m	6222023800434
FIXPU505000	5cmx5m	6223003737160
FIXPU755000	7.5cmx5m	6223003733377
FIXPU1005000	10cmx5m	6223003733384
FIXPU1505000	15cmx5m	6222023849297
FIXPU2005000	20cmx5m	6222023849303
FIXPU3005000	30cmx5m	6222023849310
FIXPU259140	2.5cmx9.14m	6222023849327
FIXPU509140	5cmx9.14m	6222023849334
FIXPU759140	7.5cmx9.14m	6222023849341
FIXPU1009140	10cmx9.14m	6222023849358
FIXPU1509140	15cmx9.14m	6222023849365
FIXPU2009140	20cmx9.14m	6222023849372
FIXPU3009140	30cmx9.14m	6222023849389
FIXPU2510000	2.5cmx10m	6223003730758
FIXPU5010000	5cmx10m	6224007257074
FIXPU7510000	7.5cmx10m	6223003734442
FIXPU10010000	10cmx10m	6224007257081
FIXPU15010000	15cmx10m	6223003730246
FIXPU20010000	20cmx10m	6223003732578
FIXPU30010000	30cmx10m	6223003730895
FIXPUSET	Assorted	6222023849396

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ANNEX 2

List of applicable standards

Version no:	01	Date:	08/06/2021
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Standard : Date	Title
EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes.
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 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.
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
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.
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
AFERA 5001	Measurement of Peel Adhesion from Stainless Steel
ASTM D 1938	Tear strength for raw materials
ASTM D 1777-96: 2007	Standard Test Method for Thickness of Textile Materials
AFERA 4013	Unwind adhesion of adhesive tapes
ASTM D 903-98: 2017	Determination of stripping load

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