



**Declaration of conformity n°** DC202  
**Revision n°** 28  
**Technical file #** 02 A

<b>Legal manufacturer</b>	Medline International France SAS 5 Rue Charles Lindbergh, 44110 Châteaubriant, France
	<b>Single Registration Number</b> FR-MF-000000676
<b>EU representative</b>	N/A
	<b>Single Registration Number</b> N/A
<b>Product range</b>	Protective Device Apparels : Headwears, Footwears, clean Air Suits, scrub suits and cover gowns
<b>Product codes</b>	See attached list
<b>Classification</b>	Class I Non-sterile, Rule 1
<b>GMDN codes</b>	See attached list

#### European Union Regulations:

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EU Regulations and/or Council Directive(s) as transposed into national laws.

**Applicable regulation:** Medical Device Regulation (EU) 2017/745 of 5 April 2017

**Conformity assessment procedure per MDR 2017/745** Annex II & III

**Notified Body** N/A

**Certificate n°** N/A

**First Issued (Place/Date)** N/A

**Applicable standards and/or Common Specifications** Listed in technical file 02 A

#### Australian Regulations:

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

All supporting documentation is retained at the premises of the manufacturer.

*Authorised Signatory:*

**Kenneth Smith** Digitally signed by Kenneth Smith  
Date: 2021.04.01 17:21:17 +02'00'

Kenneth Smith  
Senior QA/RA Manager

44110 Châteaubriant - France  
Place

01/04/2021  
Date

Document Title: FINT.434 - List of finished products for declaration of conformity



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Catalog number	GMDN code	Product description	MD Class	PPE Category	Basic UDI-DI:
CRIE1000	32297	Bouffant Cap, Spunbond Polypropylene, Green, 21", Latex Free	I NS	N/A	20080196302434
CRIE1002	32297	Bouffant Caps, White, Medium	I NS	N/A	20080196302403
CRIE1003	32297	Cap, Bouffant, Spunbond, White	I NS	N/A	20080196570420
CRIE1004	32297	Cap, Bouffant, Spunbond, Blue	I NS	N/A	20080196570444
CRIE1005	32297	Bouffant Caps, Green, Large	I NS	N/A	20884389826352
CRIE2002	13576	Shoe Cover, Blue, Latex Free	I NS	N/A	20884389826369
CRIE2010	13576	Shoe Cover, Polyethylene Material, Plain No Traction Bottom, One Size Fits Most (OSFM), Blue, Latex Free	I NS	N/A	50080196570742
CRIE2020	13576	Shoe Cover, PE Material, No Traction, Latex Free, Blue, OSFM	I NS	N/A	50884389825776
CRIE2101W	13576	Shoe cover for child, white, 32 cm	I NS	N/A	
CRIE2102W	13576	Polypropylene shoe covers	I NS	N/A	20884389825768
CRIE4000	35492	Cover gown, Yellow, Large, Elastic Wrists	I NS	N/A	50080196302398
CRIE4000B	35492	Cover gown, Blue, Large, Elastic Wrists	I NS	N/A	50884389103775
CRIE4000G	35492	Cover gown, Green, Large, Elastic Wrists	I NS	N/A	50080196321245
CRIE4001	35492	Cover gown, Yellow, X-Large, Elastic Wrists	I NS	N/A	50080196302381
CRIE4001B	35492	Cover gown, Blue, X-Large, elastic wrists	I NS	N/A	50884389103751
CRIE4001BCF	35492	Cover gown, Blue, X-Large	I NS	N/A	50080196302350
CRIE4001CF	35492	Cover gown, Yellow, X-Large, Knit Cuffs	I NS	N/A	50080196302480
CRIE4001G	35492	Cover gown, green, XL, elastic wrists	I NS	N/A	50884389103768
CRIE4001W	35492	GOWN, COVER, SPUNBOND, WHITE, XL, ELASTIC WRISTS	I NS	N/A	50888277140293
CRIE4901B	35492	Cover gown, short sleeves, blue	I NS	N/A	50888277140408
FS60000	32297	CAP, HOOD, SPUNLACE, BLUE, 28/58x60 CM,NS	I NS	N/A	20888277433813
FS60100G	32297	Surgeons Hood, green	I NS	N/A	30888277437290
FS60150B	32297	Surgeons Hood, blue	I NS	N/A	30888277437306
FS60250B	32297	Surgeons Hood with sweat band, blue	I NS	N/A	30888277437313
FS60750B	32297	CAP,TIES ON THE BACK,VISCOSE WAVY, LONG HAIR,BLUE	I NS	N/A	20888277427881
FS60850B	32297	CAP,TIES ON THE BACK,VISCOSE WAVY,SHORT HAIR,BLUE	I NS	N/A	20888277427515
FS60950B	32297	Cap, Elastic, viscose, Blue	I NS	N/A	20888277424644
FS60950G	32297	Cap, Elastic, viscose, Green	I NS	N/A	20888277424613
FS60950P	32297	Cap, Elastic, viscose, purple	I NS	N/A	20888277424620
FS60950PK	32297	Cap, Elastic, viscose, pink	I NS	N/A	20888277424637
FS60950W	32297	Cap, Elastic, viscose, white	I NS	N/A	20888277424651
FS60950Y	32297	CAP,ELASTIC,VISCOSE,YELL	I NS	N/A	20888277434315
FS61100	32297	Surgeons Hood, green	I NS	N/A	20884389144142
FS61150A	32297	Surgeons Hood, blue	I NS	N/A	00884389140522
FS61250	32297	Surgical Astro cap, blue	I NS	N/A	20884389144166
FS61300	32297	Universal Surgical Cap, Bouffant Style, green	I NS	N/A	20884389144173
FS61350	32297	Moon comfort surgical cap, bouffant design, blue	I NS	N/A	20884389144180
FS61450	32297	Ocean comfort easy tie surgeon's cap, blue	I NS	N/A	20884389144197
FS61500	32297	Planet comfort surgical cap, green	I NS	N/A	20884389144203

Retention period: 10 years after the end of life

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Catalog number	GMDN code	Product description	MD Class	PPE Category	Basic UDI-DI:
FS61550A	32297	Surgical Cap, elasticated, blue	I NS	N/A	00884389140539
FS61600	32297	Sun comfort surgical cap, green, for long hair	I NS	N/A	20884389144227
FS61650	32297	Sun comfort surgical cap, blue, for long hair	I NS	N/A	20884389144234
FS61750A	32297	Nurse Cap with ties, blue	I NS	N/A	00884389140546
FS61850A	32297	Surgical Cap, blue	I NS	N/A	00884389140553
FS61950	32297	Nurse Cap, blue	I NS	N/A	20884389144265
FS62150	32297	Cosmos Surgeon Hood, blue	I NS	N/A	20884389144272
FS62750	32297	Air nurse cap with ties, blue	I NS	N/A	20884389144319
FS63100A	32297	CAP, HOOD, SPUNBOND, GREEN	I NS	N/A	20888277424972
FS63150	32297	Cosmos light surgeon hood, blue	I NS	N/A	20884389144326
FS63150A	32297	CAP, HOOD, SPUNBOND, BLUE	I NS	N/A	20888277424965
FS63300	32297	Surgical cap, bouffant design, green	I NS	N/A	20884389144333
FS63350	32297	Surgical cap, bouffant design, blue	I NS	N/A	20884389144340
FS63360	32297	Surgical cap, bouffant design, white	I NS	N/A	20884389144357
FS63450A	32297	CAP, SPUNBOND, BLUE	I NS	N/A	20888277424958
FS64360	32297	Patient cap, white	I NS	N/A	20884389144364
FS65360	32297	Clip cap, white, one size fits most	I NS	N/A	20888277140377
FS65450	32297	CAP, CLIP, SPP, BLUE, 53 CM	I NS	N/A	20888277424996
FS65460	32297	CAP, CLIP, SPP, WHITE, 53 CM	I NS	N/A	20888277424989
FS66350	32297	Clip cap, blue, 53 cm	I NS	N/A	
FS66360	32297	Clip cap, white, 53 cm	I NS	N/A	
FS66361	32297	Clip cap for child, 40 cm, white	I NS	N/A	
FS67050	32297	Cap, Bonnet, Blue, ONE SIZE FITS MOST	I NS	N/A	20888277343211
NONE27143XL	13576	Boot Covers, Knee High, Materials: Foot: Coated Polypropylene, Foot: Multi-Layer Polypropylene, Non-Skid, Blue, X-Large Size, Latex Free	I NS	N/A	20080196416681
NONE27144	13576	Boot Covers, Knee High, Material: Coated Polypropylene, Non-Skid, Blue, Regular/Large Size, Latex Free	I NS	N/A	20080196416698
NONE27144XL	13576	Shoe Covers, Blue, XL	I NS	N/A	20080196416704
NONE28233F	32297	Bouffant Cap, Mediumweight Multi-Layer Polypropylene, Butterfly Print, 24", Latex Free	I NS	N/A	20080196570673
NONE28234P	32297	Bouffant Caps, heavyweight polypropylene material, Latex free.	I NS	N/A	20884389826376
NONE28625	32297	Surgeon Caps, Scrim Reinforced Material	I NS	N/A	20884389825737
NONE28858	13576	Shoe Cover, Multi-Layer Nonwoven Material, Non-Skid, Regular/Large Size, Pro Series, Latex Free	I NS	N/A	20080196417022
NONE28859	13576	Shoe Cover, Multi-Layer Nonwoven Material, Non-Skid, X-Large Size, Pro Series, Latex Free	I NS	N/A	20080196417039
NONE29858	13576	Shoe covers, L	I NS	N/A	00888277600150
NONE29859	13576	Shoe covers, XL	I NS	N/A	00888277600167
P2XL9110P	58382	Scrub suit pants, SMS, Blue, XXL	I NS	N/A	00888277141189
P2XL9110S	58382	Scrub suit Shirt, SMS, Blue, XXL	I NS	N/A	00888277141172
P35EB2XL	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, 2XL	I NS	N/A	
P35EBL	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, L	I NS	N/A	00888277435424
P35EBM	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, M	I NS	N/A	

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P35EBS	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, S	I NS	N/A	
P35EBXL	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, XL	I NS	N/A	
P35EBXS	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, XS	I NS	N/A	
P35EG2XL	58382	SCRUB SUITS PANTS AND SHIRT, GREEN, 2XL	I NS	N/A	
P35EGL	58382	SCRUB SUITS PANTS AND SHIRT, GREEN, L	I NS	N/A	00888277435448
P35EGM	58382	SCRUB SUITS PANTS AND SHIRT, GREEN, M	I NS	N/A	
P35EGS	58382	SCRUB SUITS PANTS AND SHIRT, GREEN, S	I NS	N/A	
P35EGXL	58382	SCRUB SUITS PANTS AND SHIRT, GREEN, XL	I NS	N/A	
P35EGXS	58382	SCRUB SUITS PANTS AND SHIRT, GREEN, XS	I NS	N/A	
P35PB2XL	58382	Scrub suit, pants and shirt, blue, 2XL	I NS	N/A	00888277341268
P35PB2XL-P	58382	Scrub suits pants, 2XL	I NS	N/A	
P35PB3XL	58382	Scrub suit, pants and shirt, blue, 3XL	I NS	N/A	00888277341275
P35PBL	58382	Scrub suit, pants and shirt, blue, L	I NS	N/A	00888277140250
P35PBL-P	58382	Scrub suits pants, L	I NS	N/A	
P35PBM	58382	Scrub suit, pants and shirt, blue, M	I NS	N/A	00888277340810
P35PBS	58382	Scrub suit, pants and shirt, blue, S	I NS	N/A	00888277341244
P35PBXL	58382	Scrub suit, pants and shirt, blue, XL	I NS	N/A	00888277140267
P35PBXS	58382	Scrub suit, pants and shirt, blue, XS	I NS	N/A	00888277341251
P35PG2XL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, 2XL	I NS	N/A	00888277424879
P35PG2XL-P	58382	SCRUB SUIT, PANT, SMS, GREEN, 2XL	I NS	N/A	00888277432171
P35PG2XL-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, 2XL	I NS	N/A	00888277432188
P35PG3XL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, 3XL	I NS	N/A	00888277424886
P35PG3XL-P	58382	SCRUB SUIT, PANT, SMS, GREEN, 3XL	I NS	N/A	00888277432195
P35PG3XL-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, 3XL	I NS	N/A	00888277432201
P35PGL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, L	I NS	N/A	00888277424855
P35PGL-P	58382	SCRUB SUIT, PANT, SMS, GREEN, L	I NS	N/A	00888277432133
P35PGL-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, L	I NS	N/A	00888277432140
P35PGM	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, M	I NS	N/A	00888277424848
P35PGM-P	58382	SCRUB SUIT, PANT, SMS, GREEN, M	I NS	N/A	00888277432119
P35PGM-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, M	I NS	N/A	00888277432126
P35PGS	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, S	I NS	N/A	00888277424831
P35PGS-P	58382	SCRUB SUIT, PANT, SMS, GREEN, S	I NS	N/A	00888277432096
P35PGS-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, S	I NS	N/A	00888277432102
P35PGXL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, XL	I NS	N/A	00888277424862
P35PGXL-P	58382	SCRUB SUIT, PANT, SMS, GREEN, XL	I NS	N/A	00888277432157
P35PGXL-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, XL	I NS	N/A	00888277432164
P35PGXS	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, XS	I NS	N/A	00888277424824
P35PGXS-P	58382	SCRUB SUIT, PANT, SMS, GREEN, XS	I NS	N/A	00888277432072
P35PGXS-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, XS	I NS	N/A	00888277432089
P42EBL	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, L	I NS	N/A	00888277435431
P42EBM	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, M	I NS	N/A	
P42EBS	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, S	I NS	N/A	
P42EBXL	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, XL	I NS	N/A	

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P42EGL	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, L	I NS	N/A	00888277435455
P42EGM	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, M	I NS	N/A	
P42EGS	58382	SCRUB SUITS PANTS AND SHIRT, BLUE, S	I NS	N/A	
P42EGXL	58382	SCRUB SUITS PANTS AND SHIRT, GREEN, XL	I NS	N/A	
P42PB2XL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, BLUE, 2XL	I NS	N/A	00888277421984
P42PB2XL-P	58382	Scrub Suit, Pant, SMS, Blue, 2XL	I NS	N/A	00888277341084
P42PB2XL-S	58382	Scrub suit, shirt, SMS, blue, 2XL	I NS	N/A	00888277340872
P42PB3XL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, BLUE, 3XL	I NS	N/A	00888277421991
P42PB3XL-P	58382	Scrub suit, pants, SMS, Blue, 3XL	I NS	N/A	00888277341091
P42PB3XL-S	58382	Scrub suit, Shirt, SMS, Blue, 3XL	I NS	N/A	00888277340889
P42PBL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, BLUE, L	I NS	N/A	00888277422134
P42PBL-P	58382	Scrub Suit, Pant, SMS, Blue, L	I NS	N/A	00888277341060
P42PBL-S	58382	Scrub suit, shirt, SMS, blue, L	I NS	N/A	00888277340858
P42PBM	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, BLUE, M	I NS	N/A	00888277421953
P42PBM-P	58382	Scrub Suit, Pant, SMS, Blue, M	I NS	N/A	00888277341053
P42PBM-S	58382	Scrub suit, shirt, SMS, blue, M	I NS	N/A	00888277340841
P42PBS	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, BLUE, S	I NS	N/A	00888277421946
P42PBS-P	58382	Scrub Suit, Pant, SMS, Blue, S	I NS	N/A	00888277341046
P42PBS-S	58382	Scrub suit, shirt, SMS, blue, S	I NS	N/A	00888277340834
P42PBXL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, BLUE, XL	I NS	N/A	00888277421977
P42PBXL-P	58382	Scrub Suit, Pant, SMS, Blue, XL	I NS	N/A	00888277341077
P42PBXL-S	58382	Scrub suit, shirt, SMS, blue, XL	I NS	N/A	00888277340865
P42PBXS	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, BLUE, XS	I NS	N/A	00888277421939
P42PBXS-P	58382	Scrub Suit, Pant, SMS, Blue, XS	I NS	N/A	00888277341039
P42PBXS-S	58382	Scrub suit, shirt, SMS, blue, XS	I NS	N/A	00888277340827
P42PG2XL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, 2XL	I NS	N/A	00888277422059
P42PG2XL-P	58382	Scrub Suit, Pant, SMS, Green, 2XL	I NS	N/A	00888277341152
P42PG2XL-S	58382	Scrub Suit, Shirt, SMS, green, 2XL	I NS	N/A	00888277340940
P42PG3XL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, 3XL	I NS	N/A	00888277422066
P42PG3XL-P	58382	Scrub suit, pants, SMS, Green, 3XL	I NS	N/A	00888277341169
P42PG3XL-S	58382	Scrub suit, Shirt, SMS, Green, 3XL	I NS	N/A	00888277340957
P42PGL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, L	I NS	N/A	00888277422035
P42PGL-P	58382	Scrub Suit, Pant, SMS, Green, L	I NS	N/A	00888277341138
P42PGL-S	58382	Scrub Suit, Shirt, SMS, green, L	I NS	N/A	00888277340926
P42PGM	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, M	I NS	N/A	00888277422028
P42PGM-P	58382	Scrub Suit, Pant, SMS, Green, M	I NS	N/A	00888277341121
P42PGM-S	58382	Scrub Suit, Shirt, SMS, green, M	I NS	N/A	00888277340919
P42PGS	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, S	I NS	N/A	00888277422011
P42PGS-P	58382	Scrub Suit, Pant, SMS, Green, S	I NS	N/A	00888277341114
P42PGS-S	58382	Scrub Suit, Shirt, SMS, green, S	I NS	N/A	00888277340902
P42PGXL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, XL	I NS	N/A	00888277422042
P42PGXL-P	58382	Scrub Suit, Pant, SMS, Green, XL	I NS	N/A	00888277341145
P42PGXL-S	58382	Scrub Suit, Shirt, SMS, green, XL	I NS	N/A	00888277340933

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P42PGXS	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, GREEN, XS	I NS	N/A	00888277422004
P42PGXS-P	58382	Scrub Suit, Pant, SMS, Green, XS	I NS	N/A	00888277341107
P42PGXS-S	58382	Scrub Suit, Shirt, SMS, green, XS	I NS	N/A	00888277340896
P42PK2XL-P	58382	SCRUB SUIT, PANTS, SMS, PINK, 2XL	I NS	N/A	00888277434601
P42PK2XL-S	58382	SCRUB SUIT, SHIRT, SMS, PINK, 2XL	I NS	N/A	00888277434618
P42PK3XL-P	58382	SCRUB SUIT, PANTS, SMS, PINK, 3XL	I NS	N/A	00888277434625
P42PK3XL-S	58382	SCRUB SUIT, SHIRT, SMS, PINK, 3XL	I NS	N/A	00888277434632
P42PKL-P	58382	SCRUB SUIT, PANTS, SMS, PINK, L	I NS	N/A	00888277434649
P42PKL-S	58382	SCRUB SUIT, SHIRT, SMS, PINK, L	I NS	N/A	00888277434656
P42PKM-P	58382	SCRUB SUIT, PANTS, SMS, PINK, M	I NS	N/A	00888277434663
P42PKM-S	58382	SCRUB SUIT, SHIRT, SMS, PINK, M	I NS	N/A	00888277434670
P42PKS-P	58382	SCRUB SUIT, PANTS, SMS, PINK, S	I NS	N/A	00888277434687
P42PKS-S	58382	SCRUB SUIT, SHIRT, SMS, PINK, S	I NS	N/A	00888277434694
P42PKXL-P	58382	SCRUB SUIT, PANTS, SMS, PINK, XL	I NS	N/A	00888277434588
P42PKXL-S	58382	SCRUB SUIT, SHIRT, SMS, PINK, XL	I NS	N/A	00888277434595
P42PKXS-P	58382	SCRUB SUIT, PANTS, SMS, PINK, XS	I NS	N/A	00888277434700
P42PKXS-S	58382	SCRUB SUIT, SHIRT, SMS, PINK, XS	I NS	N/A	00888277434717
P42PP2XL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, PURPLE, 2XL	I NS	N/A	00888277428068
P42PP2XL-P	58382	Scrub Suit, Pant, SMS, Pink, 2XL	I NS	N/A	00888277341220
P42PP2XL-S	58382	Scrub Suit, Shirt, SMS, pink, 2XL	I NS	N/A	00888277341015
P42PP3XL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, PURPLE, 3XL	I NS	N/A	00888277429911
P42PP3XL-P	58382	Scrub Suit Pants, pink, 3XL	I NS	N/A	00888277341237
P42PP3XL-S	58382	Scrub Suit Shirt, pink, 3XL	I NS	N/A	00888277341022
P42PPL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, PURPLE, L	I NS	N/A	00888277428044
P42PPL-P	58382	Scrub Suit, Pant, SMS, Pink, L	I NS	N/A	00888277341206
P42PPL-S	58382	Scrub Suit, Shirt, SMS, pink, L	I NS	N/A	00888277340995
P42PPM	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, PURPLE, M	I NS	N/A	00888277428037
P42PPM-P	58382	Scrub Suit, Pant, SMS, Pink, M	I NS	N/A	00888277341190
P42PPM-S	58382	Scrub Suit, Shirt, SMS, pink, M	I NS	N/A	00888277340988
P42PPS	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, PURPLE, S	I NS	N/A	00888277428020
P42PPS-P	58382	Scrub Suit, Pant, SMS, Pink, S	I NS	N/A	00888277341183
P42PPS-S	58382	Scrub Suit, Shirt, SMS, pink, S	I NS	N/A	00888277340971
P42PPXL	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, PURPLE, XL	I NS	N/A	00888277428051
P42PPXL-P	58382	Scrub Suit, Pant, SMS, Pink, XL	I NS	N/A	00888277341213
P42PPXL-S	58382	Scrub Suit, Shirt, SMS, pink, XL	I NS	N/A	00888277341008
P42PPXS	58382	SCRUB SUITS, PANTS AND SHIRT, SMS, PURPLE, XS	I NS	N/A	00888277428013
P42PPXS-P	58382	Scrub Suit, Pant, SMS, Pink, XS	I NS	N/A	00888277341176
P42PPXS-S	58382	Scrub Suit, Shirt, SMS, pink, XS	I NS	N/A	00888277340964
P45PB2XL-P	58382	SCRUB SUIT, PANT, SMS, BLUE, 2XL	I NS	N/A	00888277434021
P45PB2XL-S	58382	SCRUB SUIT, SHIRT, SMS, BLUE, 2XL	I NS	N/A	00888277434038
P45PB3XL-P	58382	SCRUB SUIT, PANT, SMS, BLUE, 3XL	I NS	N/A	00888277434045
P45PB3XL-S	58382	SCRUB SUIT, SHIRT, SMS, BLUE, 3XL	I NS	N/A	00888277434052
P45PBL-P	58382	SCRUB SUIT, PANT, SMS, BLUE, L	I NS	N/A	00888277425937

Retention period: 10 years after the end of life

Document Title: FINT.434 - List of finished products for declaration of conformity



DC Number: DC202

Rev: 28

Catalog number	GMDN code	Product description	MD Class	PPE Category	Basic UDI-DI:
P45PBL-S	58382	SCRUB SUIT, SHIRT, SMS, BLUE, L	I NS	N/A	00888277425944
P45PBM-P	58382	SCRUB SUIT, PANT, SMS, BLUE, M	I NS	N/A	00888277425951
P45PBM-S	58382	SCRUB SUIT, SHIRT, SMS, BLUE, M	I NS	N/A	00888277425968
P45PBS-P	58382	SCRUB SUIT, PANT, SMS, BLUE, S	I NS	N/A	00888277425975
P45PBS-S	58382	SCRUB SUIT, SHIRT, SMS, BLUE, S	I NS	N/A	00888277425982
P45PBXL-P	58382	SCRUB SUIT, PANT, SMS, BLUE, XL	I NS	N/A	00888277425999
P45PBXL-S	58382	SCRUB SUIT, SHIRT, SMS, BLUE, XL	I NS	N/A	00888277426002
P45PBXS-P	58382	SCRUB SUIT, PANT, SMS, BLUE, XS	I NS	N/A	00888277434069
P45PBXS-S	58382	SCRUB SUIT, SHIRT, SMS, BLUE, XS	I NS	N/A	00888277434076
P45PG2XL-P	58382	SCRUB SUIT, PANTS, SMS, GREEN, 2XL	I NS	N/A	00888277432706
P45PG2XL-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, 2XL	I NS	N/A	00888277432690
P45PG3XL-P	58382	SCRUB SUIT, PANTS, SMS, GREEN, 3XL	I NS	N/A	00888277432737
P45PG3XL-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, 3XL	I NS	N/A	00888277432720
P45PGL-P	58382	SCRUB SUIT, PANTS, SMS, GREEN, L	I NS	N/A	00888277432683
P45PGL-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, L	I NS	N/A	00888277432676
P45PGM-P	58382	SCRUB SUIT, PANTS, SMS, GREEN, M	I NS	N/A	00888277432669
P45PGM-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, M	I NS	N/A	00888277432652
P45PGS-P	58382	SCRUB SUIT, PANTS, SMS, GREEN, S	I NS	N/A	00888277432645
P45PGS-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, S	I NS	N/A	00888277432638
P45PGXL-P	58382	SCRUB SUIT, PANTS, SMS, GREEN, XL	I NS	N/A	00888277432621
P45PGXL-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, XL	I NS	N/A	00888277432614
P45PGXS-P	58382	SCRUB SUITS, PANTS, SMS, GREEN, XS	I NS	N/A	00888277432607
P45PGXS-S	58382	SCRUB SUIT, SHIRT, SMS, GREEN, XS	I NS	N/A	00888277432591
P50PWL-P	58382	Scrub suit, pants, white, L, Lining	I NS	N/A	00888277141462
P50PWM-P	58382	Scrub suit, pants, white, M, Lining	I NS	N/A	00888277141448
P50PWM-S	58382	Scrub suit, Shirt, white, M, Lining	I NS	N/A	00888277141455
PCLB3XL-P	58382	Clean air suits, pants, sms, blue, cuffs, 3XL	I NS	N/A	00888277606183
PCLB3XL-S	58382	Clean air suit, shirt, sms, blue, cuffs, 3XL	I NS	N/A	00888277606190
PCLBL-P	58382	Clean air suit, pants, SMS, blue, cuffs, L	I NS	N/A	00888277604134
PCLBM-P	58382	Clean air suit, Pant, SMS, blue, cuffs, M	I NS	N/A	00888277604110
PCLBM-S	58382	Clean air suit, shirt, SMS, blue, cuffs, M	I NS	N/A	00888277604103
PCLBS-P	58382	Clean air suit, pants, SMS, blue, cuffs, S	I NS	N/A	00888277604097
PCLBS-S	58382	Clean air suit, shirt, SMS, blue, cuffs, S	I NS	N/A	00888277604080
PCLBXL-P	58382	Clean air suit, pants, SMS, blue, cuffs, XL	I NS	N/A	00888277604158
PCLBXL-S	58382	Clean air suit, shirt, SMS, blue, cuffs, XL	I NS	N/A	00888277604141
PCLBXS-P	58382	Clean air suit, pants, SMS, blue, cuffs, XS	I NS	N/A	00888277604073
PCLBXS-S	58382	Clean air suit, shirt, SMS, blue, cuffs, XS	I NS	N/A	00888277604066
PCLBXXL-P	58382	Clean air suit, Pant, SMS, blue, cuffs, XXL	I NS	N/A	00888277604172
PCLBXXL-S	58382	Clean air suit, shirt, SMS, blue, cuffs, XXL	I NS	N/A	00888277604165
PL9110P	58382	Scrub suit pants, L/XL	I NS	N/A	00884389140874
PL9110S	58382	Scrub suit shirt, L/XL	I NS	N/A	00884389140881
PM9110P	58382	Scrub suit pants, M	I NS	N/A	00884389140898
PM9110S	58382	Scrub suit shirt, M	I NS	N/A	00884389140904

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DC Number: DC202

Rev: 28

Catalog number	GMDN code	Product description	MD Class	PPE Category	Basic UDI-DI:
PS9110P	58382	Scrub suit pants, S/M	I NS	N/A	00884389140911
PS9110S	58382	Scrub suit shirt, S/M	I NS	N/A	00884389140928
PXL9110P	58382	Scrub suit pants, XL	I NS	N/A	00884389140935
PXL9110S	58382	Scrub suit shirt, XL	I NS	N/A	00884389140942
PXS9110P	58382	Scrub suit pant, XS	I NS	N/A	00884389142540
PXS9110S	58382	Scrub suit shirt, XS	I NS	N/A	00884389142557

#### GMDN Code only for products classified as Medical devices.

13576	Shoe, non-conductive
32297	Cap, head, surgical, single-use
35492	Isolation gown, single-use
58382	Disposable scrub suit, non-sterile

Numer dokumentu: EU1-00019-F-00003	Rewizja: 1	Strona 1/1
Tytuł dokumentu: FINT.433 – Deklaracja zgodności		

/logo Medline/	Deklaracja zgodności nr	DC202
	Rewizja nr	28
	Dokumentacja techniczna	02 A

Producent	Medline International France SAS 5 Rue Charles Lindbergh, 44110 Chateaubriant, Francja Unikalny numer rejestracyjny: FR-MF-000000676
Upoważniony Przedstawiciel	nie ma zastosowania Unikalny numer rejestracyjny: nie ma zastosowania
Produkt – zakres	Wypożyczenie ochronne: głowy, stóp, kombinezony, ubrania operacyjne i fartuchy ochronne
Kody produktu	W dołączonym załączniku
Klasyfikacja	Klasa I niesterylna, reguła 1
Kod GMDN	W dołączony załączniku

#### Akty prawa UE

Niniejszym deklarujemy na naszą wyłączną odpowiedzialność, że ww. produkty spełniają przepisy następujących rozporządzeń lub dyrektyw(y) Rady implementowanych(ej) do krajowych porządków prawnych.	
Mające zastosowanie akty prawne:	rozporządzenie 2017/745 (MDR) z 5 kwietnia 2017 r.
Procedura oceny zgodności wg MDR 2017/745 załącznik II i III	
Jednostka notyfikowana	nie ma zastosowania
Numer certyfikatu	nie ma zastosowania
Pierwsze wydanie certyfikatu	nie ma zastosowania
Normy mające zastosowanie	wyszczególnione w dokumentacji technicznej 02 A

#### Akty prawa australijskiego

To jest deklaracja zgodności sporządzona zgodnie z klauzulą 6.6 załącznika 3 do rozporządzenia w sprawie towarów terapeutycznych (wyrobów medycznych) 2002.	
Każdy rodzaj wyrobu medycznego, do którego odnosi się dokumentacja techniczna jest zgodny z zasadniczymi wymaganiami oraz regułami klasyfikacji na czas przed jego dystrybucją.	

Wszelka dokumentacja towarzysząca przechowywana jest przez producenta.

Zatwierdzone przez:

Kenneth Smith /podpis elektroniczny/	44110 Chateaubriant – Francja	01/04/2021
Senior QA/RA Manager	Miejsce	Data

Czas przechowywania: 10 lat po cyklu życia
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