



Declaration of conformity n° DC080-B
Revision n° 04
Technical file # 01B

Legal manufacturer	Medline International France SAS 5 rue Charles Lindberg 44110 Châteaubriant, France	Single Registration Number	FR-MF-000000676
EU representative	N/A	Single Registration Number	N/A
Product range	Sterile Surgical Gowns		
Product codes	See attached list of catalog numbers		
Classification	Europe: Class I, Sterile - Rule 1 Australia: Class I (sterile)		
GMDN codes	See attachment		

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 directive:	Medical Device Directive: Council Directive 93/42/EEC of 14 June, 1993 (MDD 93/42/EEC) as amended
Conformity assessment procedure per MDD 93/42/EEC	V
Notified Body	BSI, The Netherlands – CE: 2797 (from the 4 th March 2019)
Certificate n°	CE597089
First Issued (Place/Date)	The United Kingdom, 17 th July 2013
Applicable standards and/or Common Specifications	Listed in technical file # 01B

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 declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

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

Authorised Signatory:

Kenneth Smith
Senior QA/RA Manager

Kenneth Smith
Digitally signed by Kenneth Smith
Date: 2021.09.03 17:26:20 +02'00'

44110 Châteaubriant - France
Place

03/09/2021
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:
599CEB	35091	Sterile sleeve	I sterile	N/A	
9000CEA	35091	Surgical gown with fluid proof reinforcement, S/M	I sterile	N/A	
9010CEA	35091	Surgical gown with fluid proof reinforcement, L	I sterile	N/A	
9010DCE	35091	GOWN, ECL, POLYREINFORCED, L, 120CM,DISPENSER,ST	I sterile	N/A	
9040CEA	35091	Surgical gown, with Fluid Proof Reinforcement, size XL - 130 cm	I sterile	N/A	
9040DCE	35091	GOWN, ECL, POLYREINFORCED, XL,130CM,DISPENSER,ST	I sterile	N/A	
9415CEA	35091	Surgical Gown, L	I sterile	N/A	
9505CEA	35091	Surgical Gown, S/M	I sterile	N/A	
9506CEA	35091	Surgical Gown, L	I sterile	N/A	
9506DCE	35091	GOWN, ECL, STANDARD, L, 120CM, DISPENSER,ST	I sterile	N/A	
9507CEA	35091	Surgical Gown, XL	I sterile	N/A	
9507DCE	35091	GOWN, ECL, STANDARD, XL, 130CM, DISPENSER,ST	I sterile	N/A	
9508CEA	35091	Surgical Gown, with fabric reinforcement, L	I sterile	N/A	
9509CEA	35091	Surgical Gown, with fabric reinforcement, XL	I sterile	N/A	
9509DCE	35091	GOWN, ECL, FABRIC REINFORCED, XL,130CM,DISP, ST	I sterile	N/A	
9512CEA	35091	Surgical Gown, with fabric reinforcement, XLL 150 cm	I sterile	N/A	
9512DCE	35091	GOWN, ECL, FABRIC REINFORCED, XLL,150CM,DISP,ST	I sterile	N/A	
9513CEA	35091	Surgical gown, with Fluid Proof Reinforcement, XLL	I sterile	N/A	
9513DCE	35091	GOWN,ECL,POLYREINFORCED, XLL, 150CM,DISPENSER,ST	I sterile	N/A	
9516CEA	35091	Surgical gown, XLL	I sterile	N/A	
9516DCE	35091	GOWN, ECL, STANDARD, XLL, 150CM,DISPENSER,ST	I sterile	N/A	
9539CEA	35091	Surgical Gown, with fabric reinforcement X 3, XL	I sterile	N/A	
9571CEA	35091	Surgical Gown, with fabric reinforcement, XLL	I sterile	N/A	
9571DCE	35091	GOWN, ECL, FABRIC REINFORCED, XXL,130CM,DISPENSER, ST	I sterile	N/A	
9575CEA	35091	OR Gown, Extra-Extra Large	I sterile	N/A	
9575DCE	35091	GOWN, ECL, STANDARD, XXL, 130CM,DISPENSER, ST	I sterile	N/A	
9580CE	35091	Surgical Gown, with fluid proof reinforcement, 2 XLL	I sterile	N/A	
9580DCE	35091	GOWN,ECL,POLYREINFORCED, 2XLL,170CM,DISPENSER,ST	I sterile	N/A	
9581CEA	35091	Surgical Gown, with fabric reinforcement, 2XLL	I sterile	N/A	
9581DCE	35091	GOWN, ECL, FABRIC REINFORCED,2XLL,170CM,DISP,ST	I sterile	N/A	
9585CE	35091	Gown, Ecl, Standard, 2XL, 170cm, Sterile	I sterile	N/A	
9585DCE	35091	GOWN, ECL, STANDARD, 2XLL, 170 CM,DISPENSER,ST	I sterile	N/A	
9707CE	35091	Surgical Gown	I sterile	N/A	
9709CE	35091	Surgical Gown, with fabric reinforcement	I sterile	N/A	
9712CE	35091	Surgical Gown, with fabric reinforcement	I sterile	N/A	
9716CE	35091	Surgical Gown	I sterile	N/A	
9809CE	35091	Surgical Gown, with fabric reinforcement, XL	I sterile	N/A	
9812CEA	35091	OR Gown, w/Optima Reinforcement, Extra Large, Extra Long	I sterile	N/A	
DYNJPE2000	35091	GOWN PAPER SLEEVE	I sterile	N/A	

Retention period: 10 years after the end of life

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DYNJPE2304	35091	Impervious Surgical Gown	I sterile	N/A	
DYNJPE2305	35091	GOWN, IMPERVIOUS, XLL, W/PLEAT,ST	I sterile	N/A	
E3500CEA	35091	Surgical Gown, with fluid proof reinforcement, S/M 115 cm	I sterile	N/A	
E3504CE	35091	Surgical Gown, with fabric reinforcement, S/M 115 cm	I sterile	N/A	
E3505CEA	35091	Surgical Gown, S/M115 cm	I sterile	N/A	
E3506CEA	35091	Surgical gown, ULG, standard, L, 120cm	I sterile	N/A	
E3506DCE	35091	GOWN, ULG,STANDARD,L,120CM,DISPENSER,ST	I sterile	N/A	
E3509CE	35091	Surgical Gown, with fabric reinforcement, XL 130 cm	I sterile	N/A	
E3510CEA	35091	Surgical Gown, with fluid proof reinforcement, L 120 cm	I sterile	N/A	
E3510LWCE	35091	UltraGard, Surgical gown with fluid proof reinforcement, L	I sterile	N/A	
E3513CE	35091	Surgical Gown, with fluid proof reinforcement, XLL 150 cm	I sterile	N/A	
E3513LWCE	35091	GOWN, ULG,POLYREINFORCED, XLL,150CM, ST	I sterile	N/A	
E3516CEA	35091	Surgical Gown, XLL 150 cm	I sterile	N/A	
E3516DCE	35091	GOWN, ULG,STANDARD, XLL,150CM,DISPENSER,ST	I sterile	N/A	
E3540CEA	35091	Surgical Gown, with fluid proof reinforcement, XL 140 cm	I sterile	N/A	
E3540LWCE	35091	UltraGard, Surgical Gown, with fluid proof reinforcement, XL	I sterile	N/A	
E3545CEA	35091	Surgical Gown, XL 130 cm	I sterile	N/A	
E3545DCE	35091	GOWN, ULG,STANDARD, XL,130CM,DISPENSER,ST	I sterile	N/A	
E3581CE	35091	Surgical Gown, with fluid proof reinforcement, 2 XLL	I sterile	N/A	
E3581LWCE	35091	UltraGard, Surgical Gown, with fluid proof reinforcement, 2XL	I sterile	N/A	
E3585CEA	35091	Ste back gown, 2XLL, unreinf	I sterile	N/A	
E3585DCE	35091	GOWN,ULG,STANDARD,2XLL,160CM,DISPENSER,ST	I sterile	N/A	
E3606CE	35091	GOWN, ULG,STANDARD, L,120CM,DIRECT,ST	I sterile	N/A	
E3613CE	35091	GOWN, ULG,POLYREINFORCED XLL,150CM, DIRECT,ST	I sterile	N/A	
E3616CE	35091	GOWN, ULG,STANDARD, XLL, 150CM, DIRECT,ST	I sterile	N/A	
E3640CE	35091	GOWN, ULG,POLYREINFORCED XL,140CM, DIRECT,ST	I sterile	N/A	
E3645CE	35091	GOWN, ULG,STANDARD, XL, 130CM, DIRECT,ST	I sterile	N/A	
E3681CE	35091	GOWN, ULG,POLYREINFORCED 2XLL,160CM, DIRECT,ST	I sterile	N/A	
ES597CE	35091	Sleeve with knit cuff	I sterile	N/A	
FE3545CE	35091	Gown, ULG, standard, XL,140CM,ST	I sterile	N/A	
FS3545CEA	35091	Surgical Gown	I sterile	N/A	
FS3645CE	35091	GOWN, ESS,STANDARD, XL,140CM,DIRECT,ST	I sterile	N/A	
LW32474CEB	35091	Smart IQ Breathable Impervious Surgical gown XLL	I sterile	N/A	
LW32974CEB	35091	Breathable Impervious Surgical Gown	I sterile	N/A	
LW39079CEB	35091	Breathable Impervious Surgical Gown	I sterile	N/A	
LW79041CEB	35091	Impervious Surgical Gown	I sterile	N/A	
LW89005CE	35091	Breathable impervious surgical gown	I sterile	N/A	
LW89015CEB	35091	Breathable Impervious Surgical Gown	I sterile	N/A	
LW89045CEB	35091	Breathable Impervious Surgical Gown	I sterile	N/A	
LW89915CEC	35091	Breathable Impervious Surgical Gown	I sterile	N/A	

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LW89945CEC	35091	Breathable Impervious Surgical Gown	I sterile	N/A	
LW9011CEB	35091	Impervious Surgical Gown	I sterile	N/A	
LW9041CEB	35091	Impervious Surgical Gown	I sterile	N/A	
LW9071CEB	35091	Impervious Surgical Gown	I sterile	N/A	
LW9200CEA	35091	Impervious Surgical Gown	I sterile	N/A	
LW9241CEA	35091	Impervious surgical gown, XL	I sterile	N/A	
LW9271CEA	35091	Impervious surgical gown, XXL, pe reinf	I sterile	N/A	
LW9560CEB	35091	Impervious Surgical Gown	I sterile	N/A	
LW9911CEC	35091	Impervious surgical gown, L, pe reinf	I sterile	N/A	
LW9941CEB	35091	Impervious Surgical Gown	I sterile	N/A	
LW9971CEA	35091	Impervious Surgical Gown	I sterile	N/A	
LWE3506CEA	35091	Surgical gown Essential L 120 cm	I sterile	N/A	
LWE3516CEA	35091	Surgical Gown	I sterile	N/A	
LWE3545CEA	35091	Surgical gown Essential XL 140 cm	I sterile	N/A	
LWS9505CE	35091	Surgical gown, small/medium	I sterile	N/A	
LWS9506CE	35091	Surgical gown, L	I sterile	N/A	
LWS9507CE	35091	Surgical gown, XL	I sterile	N/A	
LWS9508CE	35091	Surgical gown, with fabric reinforcement, L	I sterile	N/A	
LWS9509CE	35091	Surgical gown, with fabric reinforcement, XL	I sterile	N/A	
LWS9512CE	35091	Surgical gown, with fabric reinforcement, XLL	I sterile	N/A	
LWS9516CE	35091	Surgical gown, XLL	I sterile	N/A	
LWS9525CE	35091	Surgical gown x 2, L	I sterile	N/A	
LWS9526CE	35091	Surgical gown, XLL	I sterile	N/A	
LWS9527CE	35091	Advanced sterile back gown, XL, unreinforced	I sterile	N/A	
LWS9556CE	35091	Advanced sterile back, gown, XXL, unreinforced	I sterile	N/A	
LWS9906CE	35091	Surgical Gown, L	I sterile	N/A	
LWS9907CE	35091	Surgical Gown, XL	I sterile	N/A	
LWS9916CE	35091	Surgical Gown, XLL	I sterile	N/A	
LWS9925CE	35091	Surgical Gown	I sterile	N/A	
LWS9926CE	35091	Surgical Gown, XLL	I sterile	N/A	
OP39512CE	35091	Smart surgical gown with fabric reinforcement XLL 150 cm- raglan sleeves	I sterile	N/A	
OP39516CE	35091	Surgical Gown	I sterile	N/A	
OP9500CE	35091	Surgical Gown, with fluid proof reinforcement	I sterile	N/A	
OP9505CE	35091	Surgical Gown	I sterile	N/A	
OP9506CEA	35091	Surgical Gown, L	I sterile	N/A	
OP9507CEA	35091	Surgical Gown, XL	I sterile	N/A	
OP9508CEA	35091	Surgical Gown with fabric reinforcement, L	I sterile	N/A	
OP9508DCE	35091	GOWN, ADV,FABRIC REINFORCED,L,130CM,DISP,ST	I sterile	N/A	
OP9509CEA	35091	Surgical Gown with fabric reinforcement, XL	I sterile	N/A	
OP9509DCE	35091	GOWN,ADV,FABRIC REINFORCED,XL,140CM,DISP,ST	I sterile	N/A	
OP9510CE	35091	Surgical Gown, with fluid proof reinforcement, L	I sterile	N/A	
OP9510DCE	35091	GOWN,ADV,POLYREINFORCED,L,130CM,DISPENSER,ST	I sterile	N/A	

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OP9512CE	35091	Surgical Gown with fabric reinforcement, XLL	I sterile	N/A	
OP9512DCE	35091	GOWN, ADV,FABRIC REINFORCED,XLL,150CM,DISP,ST	I sterile	N/A	
OP9513CE	35091	Surgical Gown, with fluid proof reinforcement, XLL	I sterile	N/A	
OP9513DCE	35091	GOWN,ADV,POLYREINFORCED,XLL,150CM,DISPENSER,ST	I sterile	N/A	
OP9516CEB	35091	Smart Surgical gown, XLL	I sterile	N/A	
OP9540CE	35091	Smart-HP polyreinforced surgical gown XL (extra long body reinf.)	I sterile	N/A	
OP9540DCE	35091	GOWN,ADV,POLYREINFORCED,XL, 140CM,DISPENSER,ST	I sterile	N/A	
OP9575CE	35091	Smart Surgical gown, XXL	I sterile	N/A	
OP9581CE	35091	Surgical Gown, with fluid proof reinforcement, 2XLL	I sterile	N/A	
OP9581DCE	35091	GOWN,ADV,POLYREINFORCED,2XLL,170CM,DISPENSER,ST	I sterile	N/A	
OP9583CE	35091	Surgical Gown with fabric reinforcement, 2XLL	I sterile	N/A	
OP9583DCE	35091	GOWN,ADV,FABRIC REINFORCED, 2XLL, 170CM, DISP, ST	I sterile	N/A	
OP9585CE	35091	Surgical Gown, 2XLL	I sterile	N/A	
OP9586CE	35091	GOWN, ADV,STANDARD, 3XL,170CM, ST	I sterile	N/A	
OP9588CE	35091	GOWN, ADV,STANDARD, 2XLL,150CM, ST	I sterile	N/A	
OP9590CE	35091	Surgical gown, 3XL	I sterile	N/A	
OP9809CE	35091	Surgical Gown, with fabric reinforcement	I sterile	N/A	
OP9812CE	35091	Ste back gown, XLL, fab reinf, w/mask & f. loop	I Sterile	N/A	
S3445	35091	Essential surgical gown, XL	I sterile	N/A	
S3500CEC	35091	Surgical Gown, with fluid proof reinforcement	I sterile	N/A	
S3504CEC	35091	Surgical Gown, with fabric reinforcement, S/M 115 cm	I sterile	N/A	
S3505	35091	Essential surgical gown, S/M	I sterile	N/A	
S3505CEC	35091	Surgical Gown	I sterile	N/A	
S3506	35091	Surgical Gown	I sterile	N/A	
S3506CEC	35091	Surgical gown, essential, standard, L	I sterile	N/A	
S3506LWCE	35091	OPS Essential Surgical gown, L	I sterile	N/A	
S3507CEC	35091	Surgical Gown	I sterile	N/A	
S3508CEC	35091	Surgical gown, essential, fabric reinforced, L, 130cm	I sterile	N/A	
S3509CEC	35091	Gown, essential, fabric reinforced, XL, 130cm	I sterile	N/A	
S3510CEC	35091	Surgical Gown, with fluid proof reinforcement	I sterile	N/A	
S3511CEC	35091	Surgical Gown, with fabric reinforcement, 2XLL	I sterile	N/A	
S3512CEC	35091	Surgical Gown, with fabric reinforcement, XLL	I sterile	N/A	
S3513CEB	35091	Surgical Gown, with fluid proof reinforcement, XLL	I sterile	N/A	
S3516CEC	35091	Surgical Gown, XLL	I sterile	N/A	
S3516LWCE	35091	GOWN, ESS, STANDARD, XLL,150CM, ST	I sterile	N/A	
S3517	35091	Essential surgical gown with elastic mask S/M - 125 cm	I sterile	N/A	
S3518	35091	Essential surgical gown L 135 cm	I sterile	N/A	
S3519	35091	Essential surgical gown with elastic mask XL 140 cm	I sterile	N/A	
S3540CEC	35091	Surgical Gown, with fluid proof reinforcement, XL	I sterile	N/A	
S3545CEC	35091	Surgical Gown	I sterile	N/A	

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S3545LWCE	35091	OPS Essential Surgical gown, XL	I sterile	N/A	
S3581CEB	35091	Surgical Gown, with fluid proof reinforcement, 2 XXL	I sterile	N/A	
S3585CEC	35091	Surgical Gown, 2XLL 170 cm	I sterile	N/A	
S3585LWCE	35091	OPS Essential Surgical gown, 2XLL	I sterile	N/A	
S3587CE	35091	OPS Essential, Surgical Gown, with fluid proof reinforcement, 3XLL	I sterile	N/A	00888277435653
S3591CE	35091	OPS Essential, Surgical Gown, with fluid proof reinforcement, 3XLL	I sterile	N/A	00888277435646
S3606CE	35091	GOWN, ESS, STANDARD, L,120CM,DIRECT,ST	I sterile	N/A	
S3609CE	35091	GOWN, ESS, FABRIC REINFORCED, XL130CM DIRECT,ST	I sterile	N/A	
S3611CE	35091	GOWN, ESS, FABRIC REINF, 2XLL,160CM DIRECT,ST	I sterile	N/A	
S3612CE	35091	GOWN, ESS, FABRIC REINF, XLL,150CM,DIRECT, ST	I sterile	N/A	
S3616CE	35091	GOWN, ESS, STANDARD, XLL ,150CM, DIRECT,ST	I sterile	N/A	
S3645CE	35091	GOWN, ESS, STANDARD, XL, 130CM, DIRECT,ST	I sterile	N/A	
S3685CE	35091	GOWN, ESS, STANDARD, 2XLL,160CM,DIRECT, ST	I sterile	N/A	
S3713CE	35091	GOWN, ESS,POLYREINFORCED, XLL,150CM, ST	I Sterile	N/A	
S3740CE	35091	GOWN, ESS,POLYREINFORCED, XL,140CM, ST	I Sterile	N/A	
S3813CE	35091	GOWN, ESS,POLYREINF ,XLL,150CM, MASK, F.LOOPS,ST	I sterile	N/A	
S3840CE	35091	GOWN,ESS,POLYREINF,XL, 140CM, MASK, F.LOOPS,ST	I sterile	N/A	
S3881CE	35091	Gown, ESS, Polyreinforced, 2XL, 170CM, MASK, F.LOOPS, St	I sterile	N/A	00888277435271

GMDN Code only for products classified as Medical devices.

35091	Gown, operating room, single-use
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