



Declaration of Conformity

Declaration of conformity n°
Revision n°
Technical file #

DC080
Rev 111
01

Manufacturer	Medline International France SAS 5 rue Charles Lindbergh 44110 Châteaubriant France	Single Registration Number of the Manufacturer	N/A
Product range	Sterile procedure packs containing : gowns, surgical drapes, table cover and/or instrument cover		
Product codes	See attached reference list of catalog numbers and initial lot 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/regulation: 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 or MDR 2017/745 V

Notified Body BSI, The United Kingdom – **CE:** 0086 (before the 4th March 2019)
BSI, The Netherlands – **CE:** 2797 (from the 4th March 2019)

Certificate n° CE597089

First Issued (Place/Date) The United Kingdom, 17th July 2013

Applicable standards and/or Common Specifications Listed in technical file # 01

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

44110 Châteaubriant - France
Place

12/08/2019
Date



List of finished products for declaration of conformity

FINT.434

Revision n°05

Effective date: 23 Apr 19

Page 17 / 26

DC Number: DC080

Rev: 111

Catalog number	GMDN code	Product description	MD Class	PPE Category	Basic UDI-DI:
ICE60028S	31072	BANDED BAG, ROUND, 35X70CM	I sterile		00888277422479
ICE60030S	31072	BANDED BAG, ROUND, 40X80	I sterile		00888277422486
ICE60040S	31072	BANDED BAG, ROUND, 50X100 CM	I sterile		00888277422493
ICE60050S	31072	BANDED BAG, ROUND, 60X120CM	I sterile		00888277422509
ICE60060S	31072	BANDED BAG, ROUND, 40X80	I sterile	N/A	00888277430047
ICE63036R	31072	Banded bag, 76x91cm, rectangular	I sterile		00888277605957
ICE63628R	31072	Banded bag, 91x71cm, rectangular, With adhesive	I sterile		00888277605964
ICE63636R	31072	Banded bag, rectangular, 91x91cm	I sterile		00888277605971
ICE63654S	31072	BANDED BAG, RECTANGULAR, 95X130CM	I sterile		00888277422516
ICE64848S	31072	Banded bag, 122x122cm, rectangular	I sterile		00888277605988
ICE65656S	31072	BANDED BAG, RECTANGULAR, 142x142 CM, ST	I sterile		00888277422431
ICEBBG070	31072	BANDED BAG,ROUND,65X130 CM	I sterile		00888277422448
ICEBBG095	31072	BANDED BAG, RECTANGULAR, 95X85CM	I sterile		00888277422455
IDE1000	47783	Drape, Towle, Clear PE, 45X30CM,ADH 45CM,ST	I sterile	N/A	00888277606459
IDE1010	47783	Drape, Clear PE, 46X61CM,W/ADH,ADH 46CM,ST	I sterile		00888277606466
IDE1014	47783	DRAPE,PE,ISOLATION,317X214CM,W/INC 48X25,5CM,ST	I sterile		00888277431020
IDE1015	47783	Poly-U Drape, 122cmx132cm	I sterile		00888277421229
IDE1016	56731	Pouch, Fluid collection ,51X36CM,ADH,FILTER,ST	I sterile		00888277606473
IDE1017	47783	DRAPE,PE,ISOLATION,W/INC,317X213CM,W/POUCH,ST	I Sterile		00888277431013
IDE1017W	47783	DRAPE,PE,ISOLATION,W/INC,317X254CM,W/POUCH,ST	I Sterile		00888277606480
IDE1018	47783	Instrument pouch, Frosted,29X17cm,ADH,2 compartment, Sterile	I sterile		00888277422677
IDE1018L	47783	Instrument pouch, Frosted,46X25CM,ADH,2 compartments, Sterile	I sterile		00888277422684
IDE1019	47783	Poly-U Drape, 122cmx180cm	I sterile		00888277421236
IDE1020	47783	Fenestrated drape	I sterile		00888277421243
IDE1023	56731	Ophtalmic incise pouch,frosted PE, 48X41cm, FULL incise film, Sterile	I sterile		00888277422691
IDE1024	47783	Ophtalmic aperture pouch,frosted PE, 48X41CM,FEN incise film, sterile	I sterile		00888277422707
IDE1030	47783	Drape, Frosted, 83X129cm, Fen OVAL 8X11cm,W/INC, Sterile	I sterile		00888277422523
IDE1061	47783	Ophtalmic Drape, Frosted, 129X122cm, INC FEN 11X12cm, Sterile	I sterile		00888277422585
IDE1062	47783	Ophtalmic Drape ,ADV,129X122cm, INC FEN 11X12CM, PCH, Sterile	I sterile		00888277422530
IDE1067	33961	POUCH,SHOULDER,FROSTED,91x74CM,ADH FEN,W/FOAM,ST	I sterile		00888277429812
IDE1071	47783	Drape,Frosted,URO, 61X91cm,FEN 5cm,Finger cot, sterile	I sterile		00888277422547
IDE1072	56731	Ophtalmic pouch,frosted PE, 23X47cm, ADH FEN 11X9CM, sterile	I sterile		00888277422714
IDE1092	47783	Minor Procedure Drape	I sterile	N/A	00888277606428
IDE2057	33961	C-SECTION FLUID POUCH,ST	I sterile	N/A	00888277431006
IDE2114	56731	POUCH,CLEAR PE,FLUID,30X28CM,W/ADH,W/ WIRE,ST	I sterile	N/A	00888277422592
LW32474CEB	35091	Smart IQ Breathable Impervious Surgical gown XLL	I sterile		00888277140588
LW32974CEB	35091	Breathable Impervious Surgical Gown	I sterile		00888277140595
LW39079CEB	35091	Breathable Impervious Surgical Gown	I sterile		00888277140632
LW79041CEB	35091	Impervious Surgical Gown	I sterile		00888277140656
LW89005CE	35091	Breathable impervious surgical gown	I sterile	N/A	00888277604202

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