



Declaration of Conformity

Declaration of conformity n° DC143
Revision n° 19
Technical file # 19

Manufacturer	Medline International France SAS 5 rue Charles Lindbergh 44110 Châteaubriant - France
Product	Patient Plastics
Product Codes/ 1st Lot Number/ Scope of Application	See attached reference list of catalogue numbers and initial lot numbers
Classification	Class I non sterile
GMDN Codes	See attached list

European Union Regulations:

European Representative

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

General applicable directives: Medical Devices Directive: Council Directive 93/42/EEC of 14 June, 1993 (MDD 93/42/EEC) as amended.

Annex 93/42/EEC VII

Notified Body N/A

Certificate n° N/A

First Issued (Place/Date) N/A

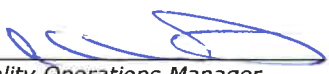
Applicable standards Listed in technical file # 19

Australian Regulations:

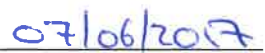
N/A

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

Authorised Signatory:

Kenneth Smith 
International Quality Operations Manager

Châteaubriant - France
Place


Date



List of finished products for declaration of conformity

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Revision n°02
Effective date: 21Jun 16
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DC Number: DC143

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Catalog number	GMDN code	Product description	MDD Class	PPE Class	First lot number CE
RM2	12143	Tray, Medium Rigid,Careset, PHANTM 150X200MM,NS	I		
30395PKA-EU	42891	CUP,PINK,120ML,GRADUATED,GALLIPOT,PP,NS	I		
05429A-EU	12143	TRAY,DEEP,24X28X5CM,BLUE,NS	I		
EMB01	36258	Emesis bag, blue, TWIST-AND-SEAL	I		
05015-EU	12143	TRAY PREP DEEP,LG,25X13X5CM,BLUE,NS	I		
05429-EU	12143	TRAY,DEEP,24X28X5CM,BLUE,NS	I		
05985-EU	12143	TRAY,MAYO,LARGE,50X39X2C M	I		
13784-EU	12143	TRAY PLATFORM,SM,28X38CM,BLUE,NS	I		
21293-EU	42891	BASIN EMESIS 700 ML,BLUE,NS	I		
30395CL-EU	42891	CUP,CLEAR,120ML,GRADUATED,GALLIPOT,PP,NS	I		
30395GR-EU	42891	CUP,GREEN,120ML,GRADUATED,GALLIPOT,PP,NS	I		
30395PK-EU	42891	CUP,PINK,120ML,GRADUATED,GALLIPOT,PP,NS	I		
47544-EU	12143	TRAY,PREP,PIGMENT FREE,43X29.5X10CM,NS	I		
47966-EU	12143	TRAY PLATFORM,LG,33X48CM,BLUE,NS	I		
47967-EU	12143	TRAY,PREP,HALF SHALLOW,LG,25X13X2.5CM,NS	I		
47968-EU	12143	TRAY,PREP,DEEP,13X13X5CM,BLUE,NS	I		
47969-EU	42891	BOWL 500ML,BLUE,GRADUATED,NS	I		
47999-EU	42891	CUP,250ML,BLUE,GRADUATED,NS	I		
48005-EU	42891	BOWL 2500ML,GRADUATED,BLUE,NS	I		
48006-EU	42891	LID FOR 8OZ BOWL	I		
48010-EU	12143	TRAY,3 COMP,24X25X5CM,BLUE,NS	I		
48011-EU	12143	TRAY,2 COMP,12X23X5CM,BLUE,NS	I		
48012-EU	42891	PITCHER,1200ML,CLEAR,GRADUATED,W/HANDLE,NS	I		
48013-EU	42891	CUP,MEDICINE,60ML,CLEAR,GRADUATED,NS	I		
48015-EU	42891	LID FOR CUP MEDICINE 60ML,NS	I		
48017-EU	42891	LID FOR BOWL 2500ML,48005,NS	I		
49475-EU	42891	CUP,MEDICINE,60ML,YELLOW,GRADUATED,NS	I		
49476-EU	42891	CUP,MEDICINE,60ML,GREEN,GRADUATED,NS	I		
49477-EU	42891	CUP,MEDICINE,60ML,BLUE,GRADUATED,NS	I		
49478-EU	42891	CUP,MEDICINE,60ML,RED,GRADUATED,NS	I		
49721-EU	12143	Tray, PLACENTA, 3000ml, 31X24x7cm, BLUE, NS	I		
50346A-EU	42891	BASIN,6000ML,RING,BLUE,NS	I		
80005-EU	12143	TRAY GUIDE/CTHR,44X31X6.5,NS	I		
80301-EU	42891	BOWL,1500ML,GRADUATED,BLUE,NS	I		
80302-EU	42891	BOWL,1000ML,GRADUATED,BLUE,NS	I		
80986	42891	BOWL,GUIDEWIRE,2500ML,W/TABS,NS	I		
80987-EU	42891	LID FOR PLACENTA BASIN 49721,NS	I		
81247-EU	36000	BOWL BONE CEMENT W/SPATULA,NS	I		
84888-EU	42891	BOWL,1000ML,PIGMENT-FREE,GRADUATED,NS	I		
84888PK-EU	42891	BOWL,1000ML,PINK,GRADUATED,NS	I		
84890-EU	12143	TRAY PREP,25X13X5CM,PIGMENT-FREE,NS	I		
84891-EU	42891	BOWL 500ML,H-6CM,D-11.7CM INTERNAL,PIGMENT-FREE,GRADUATED,NS	I		
84891Y-EU	42891	Bowl 500ml, H-6cm,D-11.7cm internal, yellow, graduated,NS	I		
84892-EU	42891	CUP,250ML,H-5.5CM,D-9CM INTERNAL,PIGMENT-FREE,GRADUATED,NS	I		
84892GR-EU	42891	CUP,250ML,GRADUATED,GREEN,NS	I		
84892PK-EU	42891	CUP,250ML,GRADUATED,RED,NS	I		
84892Y-EU	42891	CUP,250ML,GRADUATED,YELLOW, NS	I		
84895-EU	12143	TRAY PREP DEEP,13X13X5CM,PIGMENT-FREE,NS	I		
84900-EU	12143	TRAY PREP,HALF SHALLOW,LG,25X13X2.5CM,PIGMENT-FREE,NS	I		

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List of finished products for declaration of conformity

FINT.434
Revision n°02
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DC Number: DC143

Rev: 19

Catalog number	GMDN code	Product description	MDD Class	PPE Class	First lot number CE
9005-EU	42891	BASIN,800ML,KIDNEY-SHAPED,CLEAR,NS	I		
9082EU	42891	CUP,GALLIPOT,PP,60ML,CLEAR,GRADUATED,NS	I		
9082EU-GR	42891	CUP,GALLIPOT,60ML,GREEN,GRADUATED,NS	I		
96360-EU	42891	BOWL GDWIRE,2500ML,BLUE,GRADUATED W/O LID,NS	I		
BFG50346A	42891	Bowl 6000mL BLUE	I		
BFGBVJ1400	42891	Jug 1400mL, graduated	I		
BVGP150-EU	42891	CUP,CLEAR,150ML,H-5CM,D-7.5CM,GALLIPOT,PP,GRADUATED,NS	I		
BVJ1400	42891	Jug Long 1400ml	I		
BVKD1500B	42891	Kidney Dish 1500ml	I		
BVKD1500C-EU	42891	BASIN,KIDNEY,1500ML,CLEAR,NS	I		
BVKD700B-EU	42891	BASIN,KIDNEY,700ML,BLUE,NS	I		
BVKD700C	42891	Kidney Dish 700ml Clear	I		
BVKD700Y-EU	42891	BASIN,KIDNEY,700ML,YELLOW,NS	I		
BVTY2710	12143	Transfer Tray	I		
NON80328ANZEU	36258	Clean sack for sickness clean up	I		
PL1H5	12143	Tray, Large H5 cm, rigid, Careset, 300x200mm, NS	I		
PLBWGRTR120	42891	CUP,MEDICINE,120ML,CLEAR,GRADUATED,NS	I		
PLBWGRTR120-B	42891	Cup, medicine, 120 ml , blue, graduated, NS	I		
PLBWGRTR120-R	42891	CUP,MEDICINE,120ML, red,GRADUATED,NS	I		
PLBWGRTR150	42891	CUP,MEDICINE,150ML,CLEAR,GRADUATED,NS	I		
PLBWGRTR150-B	42891	CUP,MEDICINE,150ML,BLUE,GRADUATED,NS	I		
PLBWGRTR150-G	42891	CUP,MEDICINE,150ML,GREEN,GRADUATED,NS	I		
PLBWGRTR250	42891	CUP,MEDICINE,250ML,CLEAR,GRADUATED,NS	I		
PLBWGRTR90	42891	Cup, Medicine, 90ml, Clear, Graduated, NS	I		
PM1H2	12143	Tray, Medium, rigid, Careset, H2CM, 150x200mm, NS	I		
PM1H3	12143	Tray, Medium H3 cm, rigid, Careset, 150 x 200mm, NS	I		
PM2H4	12143	Tray, Medium, rigid, Careset, 150 x 200 mm, NS	I		
PM3H4	12143	Tray, Medium, rigid, Careset, 150 x 200 mm, NS	I		
PS1H3	12143	Tray small rigid, Careset, H 3cm, 75X200mm,NS	I		
RM1	12143	Cleaning tray	I		
PLBWGRTR250-B	42891	CUP,MEDICINE,250ML,CLEAR,GRADUATED,NS	I		

GMDN Code

12143	Tray, instrument
36000	Bowl, orthopaedic cement mixing
36258	Bag, emesis
42891	Bowl, general purpose, single-use

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