



Declaration of conformity n° DC265
Revision n° 14
Technical file # CES2011001

Legal manufacturer	Medline Industries, Inc. Three Lake Drive, Northfield, Illinois 60093 USA	Single Registration Number	Not available
EU representative	Medline international France SAS 5 rue Charles Lindbergh, 44110 Châteaubriant - France	Single Registration Number	FR-AR-000001814
Product range	Suction Canisters and Accessories		
Product codes	See attached list		
Classification	Medical device class I non-sterile – rule 1		
GMDN codes	See table at the end of the 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 regulation:	Medical Device Regulation (EU) 2017/745
Conformity assessment procedure per MDR 2017/745	Annex II and III
Notified Body	Not applicable
Certificate n°	Not applicable
First Issued (Place/Date)	Not applicable
Applicable standards and/or Common Specifications	See Technical file

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:

 Digitally signed by Kenneth Smith Date: 2021.05.26 16:38:04 +02'00'	44110 Châteaubriant - France Place	26/05/2021 Date
Kenneth Smith Senior QA/RA Manager		

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



DC Number: DC265

Rev: 14

Product number	GMDN code	Description	MD Class	PPE Category	Basic UDI-DI
OR53926	44942	Soft suction liner 1500cc/ml with tubing 6ft and adult vacuum control	I	N/A	10888277422278
OR916K	44942	Soft suction liner 1000cc/ml with tubing	I	N/A	10888277276215
DYNSCL3000	44942	Soft suction liner 3000cc/ml	I	N/A	10884389129548
DYNCLO1000	44943	Outer canister (for soft suction liner 1000cc/ml)	I	N/A	10080196140183
DYNCLO1500	44943	Outer canister (for soft suction liner 1500cc/ml)	I	N/A	10884389129593
DYNCLO3000	44943	Outer canister (for soft suction liner 3000cc/ml)	I	N/A	10884389129609 10884389129609
DYNSCL1000	44942	Soft suction liner 1000cc/ml	I	N/A	10080196141821
OR53916	44942	Soft suction liner 1000cc/ml with tubing and adult vacuum control	I	N/A	10888277422261
OR531	44943	Outer canister (for semi rigid suction liner 3000cc/ml)	I	N/A	10884389968123 10884389968123 10884389968123
OR53929	44942	Soft suction liner 1500cc/ml with tubing 10ft and adult vacuum control	I	N/A	10888277422285
OR54916	44942	Soft suction liner 1000cc/ml with tubing and pediatric vacuum control	I	N/A	10888277422292
OR54926	44942	Soft suction liner 1500cc/ml with tubing and pediatric vacuum control	I	N/A	10888277422308
OR1910PG	44942	Soft suction liner 1000cc/ml with solidifier	I	N/A	1088827742223 1088827742223 1088827742223 1088827742223
OR1920PG	44942	Soft suction liner 1500cc/ml with solidifier	I	N/A	10888277422230
OR395	34858	Rigid suction canister 1200cc/ml with 2 tubings	I	N/A	20888277637679
DYNDTND	16779	Tandem tubing (for soft suction liner)	I	N/A	10884389129555
OR562	44943	Outer canister (for semi rigid suction liner 1500cc/ml)	I	N/A	40888277143518
OR516K	44942	Semi rigid suction liner 1000cc/ml with tubing 5mmX6ft	I	N/A	40888277253071
OR517K	44942	Semi rigid suction liner 1000cc/ml with tubing 6mmX6ft	I	N/A	40888277253064
OR526K	44942	Semi rigid suction liner 1500cc/ml with tubing 5mmX6ft	I	N/A	40888277253088
OR527K	44942	Semi rigid suction liner 1500cc/ml with tubing 6mmX6ft	I	N/A	40888277253095
OR529K	44942	Semi rigid suction liner 1500cc/ml with tubing 6mmX10ft	I	N/A	40888277253101
DYNSCL1500	44942	Soft suction liner 1500cc/ml	I	N/A	10884389129531
OR555	44943	Outer canister (for semi rigid suction liner 1000cc/ml)	I	N/A	40888277143020
OR926K	44942	Soft suction liner 1500cc/ml with tubing 6mmX6ft	I	N/A	10888277276222
OR169	34858	Specimen trap/specimen sock shortlength 9 in (23cm)	I	N/A	1088827743391
OR510	44942	Semi rigid suction liner 1000cc/ml	I	N/A	10884389968079
OR511	44943	Outer canister (for semi rigid suction liner 1000cc/ml)	I	N/A	10884389968086
OR515	44942	Semi rigid suction liner 1500cc/ml	I	N/A	10884389968093
OR516	44943	Outer canister (for semi rigid suction liner 1500cc/ml)	I	N/A	10884389968109
OR530	44942	Semi rigid suction liner 3000cc/ml	I	N/A	10884389968116
OR539K	44942	Semi rigid suction liner 3000cc/ml with tubing 5mmX10ft	I	N/A	40888277555786

Duration of archiving: 10 years after the end of life

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



DC Number: DC265

Rev: 14

Product number	GMDN code	Description	MD Class	PPE Category	Basic UDI-DI
OR542	16779	Tandem tubing (for rigid canister system)	I	N/A	10884389968130
OR1930PG	44942	Soft suction liner 3000cc/ml with solidifier	I	N/A	10888277422247
OR312	34858	Rigid suction canister 1200cc/ml with 5mmX6' tubing	I	N/A	00888277638276 00888277638276 00888277638276 00888277638276 00888277638276 00888277638276 00888277638276 00888277638276 00888277638276 00888277638276
OR320	34858	Rigid suction canister 2000cc/ml with 5mmX6' tubing	I	N/A	00888277638283
OR319	34858	Rigid suction canister 1200cc/ml with 6mmX10ft tubing	I	N/A	10888277422216
OR896	34858	Rigid suction canister 1200cc/ml with 6mmX6ft tubing	I	N/A	20888277637686
OR220	34858	Rigid suction canister 2000cc/ml	I	N/A	10888277363359
OR139	42446	Ring holder (for rigid suction canister 2000-3000cc/ml)	I	N/A	00888277407964
OR212	34858	Rigid suction canister 1200cc/ml	I	N/A	10888277363342
OR1930	44942	Soft suction liner 3000cc/ml	I	N/A	40888277432759
DYNDCLO10T	44943	Outer canister (for soft suction liner 1000cc/ml)	I	N/A	00888277675776
DYNDCLO15T	44943	Outer Canister (for soft suction liner 1500cc/ml)	I	N/A	00888277675783
DYNDCLO30T	44943	Outer Canister (for soft suction liner 3000cc/ml)	I	N/A	00888277675790
ORLVC	34858	Canister for large fluid volume collection	I	N/A	10888277428850
OR109	42988	L-connector	I		10888277428867
OR159	42446	Ring holder (for rigid suction canister 1200cc/ml)	I	N/A	00888277407971
DYND3MNF	35375	Manifold (vacuum connection for 3 canisters set up)	I	N/A	10884389129579
OR929K	44942	Soft suction liner 1500cc/ml with tubing 6mmX10ft	I	N/A	10888277276208
OR936K	44942	Soft suction liner 3000cc/ml with tubing 6mmX6ft	I	N/A	10888277422254
OR939K	44942	Soft suction liner 3000cc/ml with tubing 6mmX10ft	I	N/A	10888277555792
OR123	34858	Specimen trap/specimen sock shortlength 4.5 in (11,5cm)	I	N/A	00888277638047
OR124	34858	Specimen trap/specimen sock shortlength 9 in (23cm)	I	N/A	00888277634254
OR230	34858	Rigid suction canister 3000cc/ml	I	N/A	10888277363366
DYND2MNF	35375	Manifold (vacuum connection for 2 canisters set up)	I	N/A	10884389129562 10884389129562
ORADAPT10	34858	Accessory Port Convertor	I	N/A	10888277427969
DYND4MNF	35375	Manifold (vacuum connection for 4 canisters set up)	I	N/A	10884389129586
OR300PEDA	34858	300cc/ml CANISTER	I	N/A	10888277424401
DYNDSCW	42446	Suction Canister Wall Mount	I	N/A	10884389129623
DYNDSCC	36801	Roll Stand - Standard	I	N/A	10884389123553
ORBASE	36801	Roll Stand - Short	I	N/A	10888277660557
OR84	34858	SPECIMEN CUP	I	N/A	00888277700218
OR125	34858	Specimen trap/specimen sock shortlength 9 in (23cm)	I	N/A	00888277424374

**DC Number:** DC265**Rev:** 14**GMDN Code only for products classified as Medical devices**

16779	Suction system tubing
34858	Suction system canister, single-use
34858	Surgical suction system collection container, single-use
35375	Valve, stopcock, general-purpose
36801	Utility trolley
42446	Suction system canister/bottle holder
42446	Suction system canister/bottle holder
42988	Low pressure tubing connector
44942	Suction system canister liner
44943	Suction system canister, reusable